Laboratory Quality Assurance Plan

Revision 7 April 4, 2003

Paragon Analytics, Inc. 225 Commerce Drive Fort Collins, Colorado 80524 970.490.1511

Approved By:	
Teller for	Olbra Hunderer
Donald F. Gipple	Debra B. Henderer
Laboratory Director	Quality Assurance Manager
Atypor 11. a orpman	PX 9 XX
Stephen M. Workman	Peter A. Gintautas, Ph.D.
Inorganics Technical Manager	Organics Dechnical Manager
Ment P. Roman	Ja-la Sum
Martin D. Brown	David C. Burns
Organics Operations Manager	Radiochemistry Operations Manager

SECTION TITLES, REVISION NUMBERS, REVISION DATES

Section Number 1.	Section Title INTRODUCTION	Revision Number 7	Revision Date 04/04/2003
2.	LABORATORY ORGANIZATION AND	7	04/04/2003
	RESPONSIBILITIES		
3.	QUALITY ASSURANCE INDICATORS	7	04/04/2003
4.	SAMPLE PRESERVATION, HOLDING	7	04/04/2003
	TIMES, AND SAMPLE HANDLING		
	POLICIES		
5.	ANALYTICAL PROCEDURES	7	04/04/2003
6.	MEASUREMENT TRACEABILTY AND	7	04/04/2003
	CALIBRATION		
7 .	PREVENTIVE MAINTENANCE	7	04/04/2003
8.	QUALITY CONTROL PROCEDURES	7	04/04/2003
9.	DATA REDUCTION, VALIDATION, AND	7	04/04/2003
	REPORTING		
10.	AUDITS	7	04/04/2003
11.	CORRECTIVE ACTIONS	7	04/04/2003
12.	PERSONNEL TRAINING	7	04/04/2003
13.	GLOSSARY, ACRONYMS, AND SYMBOLS	7	04/04/2003

APPENDICES

Appendices	(updated as necessary;	included under	separate cover,	upon request)

- A ETHICS DOCUMENTS (FORM 159, FORM 162, FORM 999)
- **B** REFERENCES
- C ORGANIZATION CHART
- D SAMPLE CONTAINER TYPES, PRESERVATION REQUIREMENTS, AND HOLDING TIMES (FORM 218)
- E CONDITION OF SAMPLE UPON RECEIPT FORM (FORM 201)
- F FACILITY DIAGRAM
- G LIST OF CAPABILITIES
- H NON-CONFORMANCE REPORT FORM (FORM 313)
- I LIST OF LABORATORY EQUIPMENT
- J LIST OF STANDARD OPERATING PROCEDURES
- K LIST OF PARAGON'S STATE AND FEDERAL CERTIFICATIONS

SECTION AND SUBSECTION TITLES

1	INTR	UDI	TO	TI	
I.	T74 T T/	UDU	J	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ノノマ

- 1.1 POLICY STATEMENT
- 1.2 CODE OF ETHICS
- 1.3 HIERARCHY OF QUALITY ASSURANCE DOCUMENTS

2. LABORATORY ORGANIZATION AND RESPONSIBILITIES

- 2.1 GENERAL REQUIREMENTS FOR LABORATORY PERSONNEL
- 2.2 KEY PERSONNEL
 - 2.2.1 LABORATORY DIRECTOR
 - 2.2.2 QUALITY ASSURANCE MANAGER
 - 2.2.3 INFORMATION SYSTEMS MANAGER
 - 2.2.4 LABORATORY INFORMATION MANAGEMENT SYSTEMS MANAGER
 - 2.2.5 RADIATION SAFETY OFFICER
 - 2.2.6 FACILITIES MANAGER
 - 2.2.7 PROGRAM DIRECTOR
 - 2.2.8 OPERATIONS MANAGER
 - 2.2.9 TECHNICAL MANAGER OR DEPARTMENT MANAGER
 - 2.2.10 WASTE COMPLIANCE OFFICER
 - 2.2.11 PROJECT MANAGER
 - 2.2.12 ANALYST OR CHEMIST OR TECHNICIAN

3. QUALITY ASSURANCE INDICATORS

- 3.1 DATA QUALITY INDICATORS
- 3.2 PRECISION
- 3.3 ACCURACY
- 3.4 REPRESENTATIVENESS

SECTION AND SUBSECTION TITLES

3.5	COMPARABILITY
3.6	COMPLETENESS
3.7	METHOD DETECTION LIMIT
3.8	METHOD QUANTITATION LIMIT OR METHOD REPORTING LIMIT
3.9	MINIMUM DETECTABLE CONCENTRATION
3.10	TOTAL PROPAGATED UNCERTAINTY
3.11	SENSITIVITY
3.12	TRACEABILITY
3.13	QUALITY ASSURANCE PROJECT PLAN (QAPjP) EXCEPTIONS

4. SAMPLE PRESERVATION, HOLDING TIMES, AND SAMPLE HANDLING POLICIES

- 4.1 INTRODUCTION
- 4.2 FIELD SUPPORT
- 4.3 SAMPLE PRESERVATION AND HOLDING TIMES
- 4.4 SAMPLE CONTAINERS
- 4.5 SAMPLE RECEIPT SCHEDULE
- 4.6 CHAIN-OF-CUSTODY
- 4.7 SAMPLE ACCEPTANCE POLICY
- 4.8 SAMPLE RECEIPT PROTOCOLS

SECTION AND SUBSECTION TITLES

4.9	SAMPLE LOGIN POLICIES AND PROCEDURES
4.フ	SAMPLE LOGIN POLICIES AND PROCEDURES

- 4.10 SAMPLE STORAGE
- 4.11 SAMPLE ACCESS, DATA ACCESS, AND INTERNAL CHAIN-OF-CUSTODY
- 4.12 SUBCONTRACTING ANALYTICAL SERVICES
- 4.13 SAMPLE DISPOSAL
- 4.14 LABORATORY FACILITES
 - 4.14.1 SAMPLE RECEIPT AREAS
 - 4.14.2 SAMPLE STORAGE AREAS
 - 4.14.3 SAMPLE PREPARATION AREAS
 - 4.14.4 DEIONIZED WATER SYSTEM

5. ANALYTICAL PROCEDURES

- 5.1 ANALYTICAL METHODS
- 5.2 METHOD COMPLIANCE
 - 5.2.1 **DEFINITION**
 - 5.2.2 UNDERSTANDING THE REGULATORY FRAMEWORK
 - 5.2.3 RESOLVING COMPLIANCE CONTRADICTIONS AND HIERARCHIES
 - 5.2.4 DISCLOSURE OF NONCOMPLIANCE
- 5.3 NON-STANDARD METHOD VALIDATION

6. MEASUREMENT TRACEABILITY AND CALIBRATION

- 6.1 GENERAL REQUIREMENTS
- 6.2 EQUIPMENT LIST

SECTION AND SUBSECTION TITLES

6.	3	TR	A	CF.	Δ	RΠ	T	ΓV	OF	C	ΔΤ	TE	P	Δ,	TI	A)	J
v.	J	11/	\boldsymbol{r}				JL.	LL	C. 11.		71	/I I	1	~	4 1	. .	

- 6.4 REFERENCE STANDARDS OF MEASUREMENT
- 6.5 TRACEABILITY OF STANDARDS, SOLVENTS, AND REAGENTS
- 6.6 GENERAL REQUIREMENTS FOR CALIBRATION
- 6.7 INSTRUMENT CALIBRATION
 6.7.1 INITIAL INSTRUMENT CALIBRATION
 6.7.2 CONTINUING INSTRUMENT CALIBRATION
- 6.8 SUPPORT EQUIPMENT

7. PREVENTIVE MAINTENANCE

- 7.1 MAINTENANCE RESPONSIBILITIES
- 7.2 MAINTENANCE DOCUMENTATION
- 7.3 MAINTENANCE SCHEDULES
- 7.4 SPARE PARTS
- 7.5 CONTINGENCY PLAN

8. QUALITY CONTROL PROCEDURES

- 8.1 DEFINITION OF BATCH
 - 8.1.1 PREPARATION BATCH
 - 8.1.2 ANALYSIS BATCH
- 8.2 PREPARATION BATCH QC SAMPLES AND STANDARDS -- DEFINITON AND USE
 8.2.1 METHOD BLANK

SECTION AND SUBSECTION TITLES

ጸ	2	2	T.A	BC	R A	T	OR	V	ഗ	NT	R	Λī	2	Δλ	Æ	F
U,	· 🚣 .	_	105	\mathbf{u}	\mathbf{m}	νт,	\mathbf{v}	1	\mathbf{v}		· N	U	⊸ .⊃.	MI	71 F L	æ

- 8.2.3 MATRIX SPIKE/MATRIX SPIKE REPLICATE
- 8.2.4 SAMPLE DUPLICATE
- 8.2.5 SURROGATE SPIKES
- 8.2.6 CHEMICAL YIELD MONITORS

8.3 CONTROL CHARTS

- 8.3.1 ACCURACY CONTROL CHARTS
- 8.3.2 OUTLIER REJECTION
- 8.4 SECOND COLUMN OR SECOND DETECTOR CONFIRMATION PROCEDURES
- 8.5 MANUAL RE-INTEGRATION POLICIES AND PRCEDURES

9. DATA REDUCTION, VALIDATION, AND REPORTING

- 9.1 CORRECTION OF ERRORS IN DOCUMENTS
- 9.2 DATA REDUCTION
- 9.3 DOCUMENTATION OF RAW DATA
- 9.4 DATA REVIEW
- 9.5 DATA REPORTING
 - 9.5.1 FACSIMILE REPORTS
 - 9.5.2 ELECTRONIC DATA DELIVERABLES
 - 9.5.3 HARDCOPY DATA PACKAGES
 - 9.5.3.1 COVER LETTER
 - 9.5.3.2 REPORT FORMAT
 - 9.5.3.3 QUALITY CONTROL REPORT
- 9.6 DATA QUALIFIERS FLAGGING CODES
- 9.7 RECORDS AND DATA STORAGE

SECTION AND SUBSECTION TITLES

9.8	REVIEW, REVISION, AND DISTRIBUTION (OF
	QUALITY ASSURANCE DOCUMENTS	

- 9.9 PROCEDURES FOR HANDLING UNACCEPTABLE DATA
- 9.10 COMPLAINTS
- 9.11 CONFIDENTIALITY

10. AUDITS

- 10.1 INTERNAL AUDITS
 - 10.1.1 INTERNAL TECHNICAL AND SYSTEMS AUDITS
 - 10.1.2 PROFICIENCY TESTING STUDIES
- 10.2 MANAGERIAL REVIEW
- 10.3 EXTERNAL AUDITS

11. CORRECTIVE ACTIONS

- 11.1 INTRODUCTION
- 11.2 RESPONSIBILITIES FOR CORRECTIVE ACTION
 - 11.2.1 ANALYST
 - 11.2.2 DEPARTMENT MANAGER OR TECHNICAL MANAGER
 - 11.2.3 PROJECT MANAGER
 - 11.2.4 QUALITY ASSURANCE MANAGER

12. PERSONNEL TRAINING

- 12.1 ORIENTATION
- 12.2 ANALYTICAL TRAINING
 - 12.2.1 INITIAL DEMONSTRATION OF CAPABILITY

SECTION AND SUBSECTION TITLES

- 12.2.2 CONTINUING DEMONSTRATION OF CAPABILITY
 12.2.2.1 METHOD DETECTION LIMIT (MDL) STUDIES
 12.2.2.2 PROFICIENCY TESTING SAMPLES
- 12.3 TRAINING RECORDS
- 13. GLOSSARY, ACRONYMS, AND SYMBOLS
 - 13.1 GLOSSARY
 - 13.2 ACRONYMS
 - 13.3 SYMBOLS

1. INTRODUCTION

1.1 POLICY STATEMENT

This Laboratory Quality Assurance Plan (LQAP) defines the quality assurance program and policies for Paragon Analytics, Inc. (Paragon). Paragon is located in Fort Collins, Colorado and is incorporated under the laws of the State of Colorado. Paragon has no other corporate affiliation nor is it part of a network. Paragon is a veteran-owned business (TIN 84-1333361, NAICS code 541380, SIC code 8734).

Paragon performs analyses for organic, inorganic, and radiological constituents in a variety of matrices. The management team's integrated approach to quality assurance, client service, and operations enables Paragon to produce compliant data that meet all technical and service requirements as prescribed by our clients. Paragon is committed to producing data of known, documented, and appropriate quality in accordance with standards developed by the National Environmental Laboratory Accreditation Conference (NELAC) and any applicable state or US Environmental Protection Agency (EPA) regulations and requirements. Therefore, Paragon performs analyses according to various federal and state quality assurance/quality control (QA/QC) programs and analyzes samples in strict accordance with promulgated methodologies, including:

- US EPA, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846);
- US EPA, Methods for Chemical Analysis of Waters and Wastes (MCAWW);
- American Public Health Association, Standard Methods for the Examination of Water and Wastewater (SM);
- American Society for Testing and Materials, Annual Book of ASTM Standards,
 Section 11 Water and Environmental Technology;
- US EPA, Contract Laboratory Program Statement of Work (CLP SOW); and
- US, Code of Federal Regulations (40CFR).

Paragon specializes in serving the Department of Defense (DoD), the Department of Energy (DOE), and architect-engineering firms. Paragon routinely provides hardcopy data packages and electronic data deliverables that are easily validated by external validators.

1.2 CODE OF ETHICS

Paragon is responsible for creating a work environment that enables all employees to perform their duties in an ethical manner. It is Paragon's expectation that all employees exhibit professionalism and respect for clients and each other in all interactions and tasks. Paragon requires that each employee abide by the following guidelines:

- Every Paragon employee is responsible for the propriety and consequences of his or her actions.
- Every Paragon employee is required to conduct him or herself in a professional manner toward all clients, regulators, auditors, vendors, and other employees.
 Professional conduct relates to honesty, integrity, respect, and tolerance for cultural diversity.
- Every Paragon employee shall perform all assigned duties in accordance with
 Paragon's established quality assurance policies and quality control procedures
 that have been developed in substantial conformity with contractual and regulatory
 requirements.
- Paragon expects all employees to use professional judgment and to document all situations thoroughly. It is the responsibility of each Paragon employee to consult the Department Manager or Quality Assurance Manager when atypical or unusual situations occur and to disclose and document our decision-making process.
- Every employee must disclose any instance of noncompliance. Paragon reports all noncompliance issues to the client, if data are affected by the noncompliance.
- It is the responsibility of each Paragon employee to report any suspicion of unethical conduct to the Quality Assurance Manager or the Laboratory Director.

Strict adherence to Paragon's Code of Ethics is essential to the reputation and continued health of the business. All Paragon employees are required to acknowledge their responsibility and intent to behave in an ethical manner by attesting to the requirements described above. *Appendix A* includes ethics documents that every employee is required to review and sign upon hire and annually thereafter.

The following list provides examples of improper, unethical, or illegal practices that Paragon does not tolerate:

- Improper use of manual integrations performed to meet calibration or method quality control criteria (e.g., peak shaving or peak enhancement performed solely to meet quality control requirements).
- Intentional misrepresentation of the date or time of analysis (e.g., intentionally
 resetting a computer system's or instrument's date and/or time to make it appear that a
 date/time requirement has been achieved).
- Falsification of records to meet method requirements (e.g., sample records, logbooks, sample results, electronic records).
- Reporting results without analyses to support the results (i.e., dry labbing).
- Selective exclusion of data to meet quality control criteria (e.g., eliminating initial calibration points without technical justification).
- Misrepresentation of laboratory performance by presenting calibration data or quality control limits within data reports that are not relevant to the results being reported.
- Notation of matrix interference as basis for exceeding acceptance limits in interference-free matrices.
- Unwarranted manipulation of computer software (e.g., improper background subtraction to meet ion abundance criteria for GC/MS tuning compounds; chromatographic baseline manipulations).

- Improper alteration of analytical conditions from standard analysis to sample analysis
 (e.g., modifying electron-multiplier voltage, changing temperature or eluent profiles to
 shorten analytical run time).
- Misrepresentation of quality control samples (e.g., adding surrogates or tracers after sample extraction, omitting preparation steps for quality control samples; over- or under-spiking).
- Reporting results from the analysis of one sample for another (file substitution).
- Intentional plagiarism or willful misrepresentation of another employee's work as one's own (e.g., Initial or Continuing Demonstration of Capability Study (IDOC, CDOC) or Proficiency Testing (PT) Study).

1.3 HIERARCHY OF QUALITY ASSURANCE DOCUMENTS

Paragon recognizes a hierarchy of documents that provides comprehensive definition and flexible coverage of all quality assurance requirements and quality control procedures.

This LQAP is the primary document that describes Paragon's quality assurance program and policies. All programs, policies, and procedures have been developed and implemented in accordance with the NELAC standard approved in May 2001 and applicable EPA requirements, regulations, guidance, and technical standards. This document provides a framework for the quality assurance program and policies and quality control procedures followed by Paragon in the absence of project-specific requirements. Paragon has prepared this LQAP in accordance with the reference documents cited in *Appendix B*.

The second kind of document in this hierarchy is a standard operating procedure (SOP). An SOP defines the QA/QC requirements for each method and describes in detail how personnel perform procedures and evaluate data. Where SOPs differ from concepts

discussed in the LQAP, the requirements of the SOPs supersede the requirements of the LQAP.

The last and most specific document in this hierarchy is the Quality Assurance Project Plan (QAPjP). This document often has a limited scope and addresses only those quality assurance requirements and quality control criteria required for a specific project. Usually, the client prepares a QAPjP and provides a copy to the contract laboratory. Paragon's Project Manager, Technical Manager, and Department Manager work together to distill the project-specific requirements via our Laboratory Information Management System (LIMS) Program Specifications for the laboratory's reference. When the requirements of the QAPjP differ from those stated in the SOPs and/or LQAP, the project-specific requirements supersede the others.

2. LABORATORY ORGANIZATION AND RESPONSIBILITIES

This section provides an overview of Paragon's organization and defines key personnel, their responsibilities, and the lines of communication between these employees. An organization chart that illustrates reporting relationships is provided in *Appendix C*.

In the event of a temporary absence, key personnel must notify all employees of their absence and reassign their duties to another employee who is qualified to perform the assigned duties. For example, a Project Manager may assign another Project Manager to cover his/her duties; a Department Manager may assign a senior analyst to cover his/her duties within the department; and the Laboratory Director may assign the Operations Manager to cover his duties.

2.1 GENERAL REQUIREMENTS FOR LABORATORY PERSONNEL

Paragon maintains sufficient personnel to perform analytical services for our clients. Each employee must have a combination of experience and education that enables him/her to demonstrate a specific knowledge of his/her job function and a general knowledge of laboratory operations, test methods, quality assurance policies and quality control procedures, and records management. All personnel are responsible for complying with all quality assurance policies and quality control procedures that pertain to their assigned duties.

2.2 KEY PERSONNEL

2.2.1 LABORATORY DIRECTOR

The Laboratory Director (and/or designee) is responsible for:

- All laboratory operations, including: business functions such as marketing, sales, and financial issues; technical functions such as sample control, analysis, data management; and quality assurance;
- Supervising all personnel through Department Managers who ensure that quality
 assurance policies and quality control procedures are being performed and that any
 nonconformances or discrepancies are documented and remedied properly and
 promptly;
- Defining the minimum level of education, experience, and skills necessary for all positions in the laboratory;
- Documenting the quality of all data reported by the laboratory;
- Ensuring that the laboratory has the appropriate resources and facilities to perform analytical services;
- Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory;
- Ensuring that only those vendors and supplies that are of adequate quality are used; and
- Ensuring that corrective actions relating to findings from internal and external audits are completed in a timely fashion.

2.2.2 QUALITY ASSURANCE MANAGER

The Quality Assurance Manager reports to the Laboratory Director. The Quality

Assurance Manager is independent of daily operations and production requirements.

Therefore, the Quality Assurance Manager is able to evaluate data objectively and perform

assessments without production influence. The Quality Assurance Manager has authority to stop work if systems are sufficiently out of control to compromise the integrity of the data generated. The Quality Assurance Manager shall have: documented training and/or experience in QA/QC procedures; knowledge of quality systems as defined by NELAC; and a general knowledge of the analytical test methods for which data review is performed. The Quality Assurance Manager (and/or designee) is responsible for:

- Defining and implementing the quality system;
- Developing and maintaining a pro-active program for prevention and detection of improper, unethical, or illegal practices (e.g., single- or double-blind proficiency testing studies, electronic data and magnetic tape audits, SOPs that identify appropriate and inappropriate laboratory and data manipulation practices):
- Representing Paragon's interests at technical meetings (e.g., NELAC/INELA, ACIL);
- Performing post-invoice review of 10% of all data reported and notifying
 Department Managers of trends detected;
- Overseeing or conducting internal audits of the entire operation annually (technical, system, electronic);
- Performing an annual Managerial Review;
- Notifying Department Managers of nonconformances and approving corrective actions;
- Ensuring continuous improvement of laboratory procedures via training, control charts, proficiency testing studies, internal audits, and external audits:
- Coordinating the laboratory's certification program participation in state and federal agencies;
- Facilitating external audits;
- Coordinating and preparing external and internal audit responses and corrective actions;

- Reviewing Requests For Proposal (RFPs) to ensure compliance with required
 QA/QC practices and supporting the preparation of proposals;
- Revising the LQAP annually in accordance with industry standards;
- Revising Paragon's Statement of Qualifications (SOQ) semi-annually;
- Managing the laboratory's participation in proficiency testing studies;
- Scheduling the review and distribution and maintaining distribution records of controlled documents;
- Scheduling and approving annual Method Detection Limit (MDL) studies;
- Managing the annual calibration and/or verification of support equipment (e.g., weights, thermometers, balances); and
- Maintaining an archival system for data records.

2.2.3 INFORMATION SYSTEMS MANAGER

The Information Systems (IS) Manager reports to the Laboratory Director. The IS Manager is responsible for supporting the Laboratory Information Management System (LIMS) and network, which serve the needs of the technical, business, and management functions of the laboratory. The IS Manager (and/or designee) is responsible for:

- Supervising Information Services personnel;
- Managing and maintaining the laboratory computer system. This function includes
 establishing network server structure, security, maintenance, and backup
 procedures;
- Documenting operating procedures through SOPs or manuals;
- Serving as a technical resource on computer related issues;
- Analyzing information flow in the laboratory and suggesting the most effective
 hardware, application software, and/or programming changes as solutions to meet
 long term customer requirements. Implementing those changes in data by
 purchase of hardware and applications software; or by software development,
 using the appropriate tools and methodology;

- Supervising recovery of all systems in the event of a disaster;
- Maintaining and implementing existing and future communications systems,
 including all internet and telephone systems; and
- Determining specific customer requirements for electronic data format and then developing the interface to achieve the requirements for data submission.

2.2.4 LABORATORY INFORMATION MANAGEMENT SYSTEMS MANAGER

The Laboratory Information Management Systems (LIMS) Manager reports to the Laboratory Director. This manager (and/or designee) is responsible for:

- Designing and developing information systems that relate to data capture, data processing, or any activity that requires interaction with the LIMS;
- Maintaining and supporting applications that access LIMS;
- Maintaining and supporting database back-end applications used for LIMS;
- Providing user documentation for all LIMS related applications;
- Providing training for all LIMS applications;
- Coordinating all efforts to automate and improve systems and processes throughout the laboratory;
- Analyzing information flow in the laboratory and suggesting the most effective
 application software, and/or programming changes as solutions to meet long term
 customer requirements. Implementing those changes in data by applications
 software or by software development, using the appropriate tools and
 methodology;
- Determining specific customer requirements for electronic data format and then developing the interface to achieve the requirements for data submission; and
- Managing all deliverable formats provided to clients (hardcopy, electronic).

2.2.5 RADIATION SAFETY OFFICER

The Radiation Safety Officer reports to the Laboratory Director. This manager is responsible for all aspects of acquiring and handling radioactive materials. The Radiation Safety Officer (and/or designee) is responsible for:

- Applying for radioactive materials license and preparing radioactive materials license renewal applications;
- Ensuring compliance with Colorado Rules and Regulations pertaining to radiation control;
- Managing radiation dosimetry program;
- Maintaining radioactive material inventory;
- Ordering radioactive materials standards and sources;
- Managing radioactive materials releases to the sanitary sewer;
- Ensuring that radioactive materials are transferred only to facilities that possess a radioactive materials license;
- Ensuring that radioactive materials are transported in accord with all federal and state regulations; and
- Assisting in acquisition and approval of the financial insurance bond.

2.2.6 FACILITIES MANAGER

The Facilities Manager reports to the Laboratory Director. This manager is responsible for day-to-day management of the building. The Facilities Manager (and/or designee) is responsible for:

- Coordinating heating, ventilation, and air-conditioning (HVAC) systems operation and maintenance;
- Managing HVAC vendors;
- Coordinating repair of HVAC systems in order to minimize downtime;
- Coordinating maintenance and repairs to electrical system;

- Coordinating repairs to building (e.g., doors, locks, windows, cabinetry);
- Maintaining the uninterruptible power supply (UPS) system;
- Maintaining in-house vacuum system;
- · Scheduling repairs as needed; and
- Responding to security system alarms and fire alarms on a 24-hour basis.

2.2.7 PROGRAM DIRECTOR

The Program Director reports to the Laboratory Director. The Program Director (and/or designee) is responsible for:

- Providing feedback to laboratory operations including areas such as sample control, preparations, analysis, data management, data review and client service;
- Recommending acquisition of personnel, capital resources, and facilities to aid in increasing or developing analytical services;
- Evaluating new methods and technologies and recommending development to the
 Operations Manager for those that improve Paragon's ability to meet client needs;
- Reviewing RFPs;
- Preparing and submitting proposals;
- Interacting with the Quality Assurance, Information Technology, and Health and Safety Departments to ensure that the laboratory is capable of complying with client or regulatory requirements;
- Overseeing programs to ensure that clients' technical and service requirements are consistently achieved;
- Conducting marketing and business development activities; and
- Performing market surveys to determine client satisfaction and value of developing new methods and technologies.

2.2.8 OPERATIONS MANAGER

The Operations Manager reports to the Laboratory Director. The Operations Manager (and/or designee) is responsible for:

- Overseeing laboratory operations, including all technical areas such as sample control, preparations, analysis, data management, and data review;
- Supervising personnel through Department Managers who ensure that all analyses are performed according to standard operating procedures and prescribed quality control requirements;
- Acquiring the appropriate personnel, capital resources, and facilities to perform analytical services;
- Evaluating new methods and technologies and developing those that improve Paragon's ability to meet client needs;
- Reviewing RFPs;
- Interacting with the Sales and Quality Assurance Departments to ensure that the laboratory is capable of complying with client or regulatory requirements;
- Overseeing production to ensure that financial goals are achieved; and
- Overseeing projects to ensure that clients' technical and service requirements are consistently achieved.

2.2.9 TECHNICAL MANAGER OR DEPARTMENT MANAGER

Technical Managers and Department Managers report to the Operations Manager. These managers exercise day-to-day supervision of laboratory personnel, procedures, and reporting of results. They maintain technical expertise in their area of specialization (e.g., organics, inorganics, radiochemistry). Technical Managers and Department Managers (and/or designee) are responsible for:

- Certifying that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited;
- Monitoring standards of performance in quality assurance and quality control;

- Monitoring the validity of the analyses performed and data generated in the laboratory to ensure the production of compliant data;
- Assigning job tasks and prioritizing analyses;
- Providing technical education and training to personnel;
- Ensuring that documentation of training is up to date;
- Ensuring that corrective actions are developed, documented, and implemented for external and internal audit findings and PT standard failures;
- Coordinating and approving the purchase of reagents, standards, glassware, and equipment that meet requirements;
- Developing and implementing a preventive maintenance program for instrumentation in their laboratory;
- Ensuring that all equipment is maintained, serviced, and properly calibrated;
- Providing input to the Operations Manager regarding methodologies, personnel resources, software, and instrumentation;
- Maintaining current, compliant MDL studies for all methods, matrices, analytes, columns, and instruments;
- Ensuring that all personnel demonstrate proficiency in the analyses for which they are responsible before analyzing samples (e.g., perform Initial Demonstration of Capability studies) and documenting this demonstration of proficiency; and
- Reviewing and revising (if appropriate) assigned SOPs annually to ensure that
 SOPs are compliant with promulgated methodologies and reflect current practice.

2.2.10 WASTE COMPLIANCE OFFICER

The Waste Compliance Officer reports to the Operations Manager and serves as the primary point of contact for all matters related to waste collection and disposal. This manager (and/or designee) is responsible for:

Overseeing all waste disposal operations performed by Paragon;

- Ensuring compliance with federal, state, and local regulations for waste handling and disposal in accord with RCRA, TSCA, and radioactive waste disposal regulations;
- Maintaining Satellite Accumulation Areas (SAAs) and 90-Day Storage Areas;
- Supervising the Sample Control Department;
- Managing sanitary sewer releases;
- Implementing waste reduction procedures;
- Managing hazardous waste shipments to Temporary Storage and Disposal Facilities (TSDFs);
- Managing the accumulation or radioactive waste in the laboratory;
- Managing sample archives and the return of samples and sample residues to clients;
- Training personnel on proper techniques for sample handling and waste disposal, according to standards implemented by federal, state, and local authorities;
- Providing health and safety training for new employees;
- Performing routine surveillances of laboratory for radioactivity; and
- Managing prescreen analyses that provide initial characterization of samples (e.g., radioactive, mixed, hazardous, nonhazardous).

2.2.11 PROJECT MANAGER

The Project Manager reports to the Operations Manager and serves as the primary point of contact between clients and Paragon. This manager (and/or designee) is responsible for:

- Managing and coordinating the laboratory's performance after contract award, by defining technical and service requirements for personnel via LIMS;
- Reviewing all final reports for completeness, compliance with project requirements, clerical accuracy, and reasonableness;

- Interacting with clients and personnel to ensure that technical criteria and client service needs are met;
- Monitoring holding times (if appropriate) and deliverable deadlines for all project sample analyses;
- Reviewing and approving any nonconformances reported by the laboratory and notifying the client, if appropriate;
- Communicating with clients pro-actively to ensure that all client service and technical concerns are resolved promptly; and
- Communicating to personnel any potential need for new or improved capabilities based on clients' feedback.

2.2.12 ANALYST OR CHEMIST OR TECHNICIAN

An analyst or chemist or technician reports to a Department Manager or Technical Manager. This employee performs work in accordance with Paragon's controlled documents (e.g., SOPs, LQAP) and project-specific requirements (as defined in LIMS). Paragon believes that quality begins at the bench. Accordingly, these employees are key contributors to Paragon's success. An analyst or chemist or technician is responsible for:

- Performing an annual review of assigned SOPs and the LQAP;
- Demonstrating proficiency in the analyses for which they are responsible before
 analyzing samples (e.g., performing acceptable Initial Demonstration of Capability
 studies) and documenting this demonstration of proficiency;
- Performing analyses and interpreting and reviewing data according to established procedures as described in Paragon's controlled documents;
- Recording all data accurately, directly, and promptly;
- Maintaining and repairing instrumentation;
- Disclosing all instances of nonconformances promptly and in writing via the NCR
 Form (Form 313);

- Complying with all quality assurance policies and quality control requirements that pertain to their job function;
- Participating in training sessions; and
- Complying with all health, safety, and waste disposal requirements, as applicable.

3. QUALITY ASSURANCE INDICATORS

Paragon's objective is to develop and implement policies and procedures that will provide results of known, documented, and appropriate quality. This Laboratory Quality Assurance Plan (LQAP) defines *policies* for the analysis, documentation, evaluation, validation, and reporting of data. Standard Operating Procedures (SOPs) describe specific, detailed *procedures* for chain of custody, calibration of instruments, analysis, reporting, quality control, audits, preventive maintenance, and corrective actions.

In order to produce data of known, documented, and appropriate quality, Paragon:

- Maintains an effective quality assurance program that measures and verifies laboratory performance;
- Provides a Quality Assurance Department independent of the operational groups that has the responsibility and authority to audit the laboratory and develop and enforce corrective action procedures;
- Evaluates technical and service requirements of all requests to provide
 analytical services <u>before</u> accepting samples from a client/project. This
 evaluation includes a review of: facilities, instrumentation, staffing, turnaround
 times, and any project-specific quality control or reporting requirements;
- Performs all analyses according to promulgated methods or methods developed and validated by Paragon and documented in SOPs;
- Provides sufficient flexibility to allow controlled changes in routine methodology in order to achieve client-specific data requirements as prescribed in project-specific quality plans;
- Demonstrates initial demonstration of capability (IDOC) and continuing demonstration of capability (CDOC) with all methods according to Appendix C of the NELAC 2001 manual;

- Recognizes as soon as possible and discloses and corrects any factors that adversely affect data quality; and
- Maintains complete records of sample submittal, raw data, laboratory performance, and completed analyses to support reported data.

3.1 DATA QUALITY INDICATORS

Data Quality Indicators (DQIs) are qualitative and quantitative statements developed by data users that specify the quality of data from field and laboratory data collection activities in order to support specific decisions or regulatory actions. The DQIs describe what data are needed, why the data are needed, and how the data will be used to address the problem being investigated. DQIs also establish qualitative and quantitative goals that allow the data user to determine whether the data are of sufficient quality for the intended application.

The principal DQIs are: precision, accuracy (bias), representativeness, completeness, and comparability (PARCCs parameters). The following sections describe the definition and application of these parameters as defined by various sources, in particular the US Army Corps of Engineers *EM 200-1-3*, *Appendix I*, *Shell For Analytical Chemistry*Requirements. The quality assurance and quality control protocols used for the majority of analyses are adopted from the following sources that contain detailed descriptions of the quality control measures routinely employed: SW-846 methodologies, 40 CFR methodologies, and US EPA CLP SOW (Organics and Inorganics).

3.2 PRECISION

Precision is an expression of the reproducibility or degree of mutual agreement among independent measurements as the result of repeated application of the same process under similar conditions. Precision refers to the distribution of a set of reported values about the

mean, or the closeness of agreement between individual tests results obtained under prescribed conditions. Precision reflects random error and may be affected by systematic error. Precision characterizes the natural variation of the matrix and the contamination that may vary within that matrix. For chemical parameters that do not allow homogenization prior to analysis, one must review precision values carefully (e.g., volatile organics analysis).

Analytical precision is a measurement of the variability associated with duplicate or replicate analyses of the same sample in the laboratory and is determined by analysis of laboratory duplicates. Total precision is a measurement of the variability associated with the entire sampling and analysis process. It is determined by analysis of duplicate or replicate field samples and incorporates variability introduced by both the laboratory and field operations.

Precision must be interpreted by taking into consideration the possible sources of variability. Duplicate samples or spiked duplicate samples are analyzed to assess field and analytical precision and the results are assessed using the relative percent difference (RPD) between duplicate measurements. Precision objectives are presented for each analytical method.

Analytical precision is evaluated by matrix spike/matrix spike duplicates (MS/MSD), by laboratory control sample pairs (LCS/LCSD), or by duplicate samples. Precision is independent of the bias or accuracy of the analysis and reflects only the degree to which the measurements agree with one another, not the degree to which they agree with the true or accepted value of the parameter measured.

Precision is calculated in terms of Relative Percent Difference (RPD), which may be calculated as follows:

$$RPD(\%) = \frac{X_1 - X_2}{(X_1 + X_2)/2}$$
 (100)

Where:

RPD = Relative Percent Difference

 X_1 , X_2 = analyte value of sample 1 and sample 2

RPDs are compared to the control limits for the analysis. Sample homogeneity/non-homogeneity is an important factor that influences the precision of duplicate samples for stable chemistry analyses.

For radiochemical analyses, precision is measured in terms of Duplicate Error Ratio (DER), which is calculated as follows:

$$DER = \frac{|S - D|}{2 * \sqrt{\sigma_S^2 + \sigma_D^2}}$$

Where:

DER = Duplicate Error Ratio

S, D = analyte values of (S) ample and (D) uplicate

 σ = One sigma error value associated with sample result

DERs are compared to the control limits for the analysis. Sample homogeneity/non-homogeneity is an important factor that influences the precision of duplicate samples for radiological analyses.

3.3 ACCURACY

Accuracy is an expression of agreement between the measured and known or accepted reference values. Accuracy is the measure of the closeness of an observed value to the "true" value (e.g., theoretical or reference value or population mean). Accuracy is influenced by random error and systematic error (bias) that occur during sampling and

analytical procedures; therefore, accuracy reflects the total error associated with a measurement. A measurement is accurate when the value reported does not differ significantly from the known concentration of the spike or standard.

Accuracy is typically measured by determining the percent recovery of known target analytes that are spiked into a field sample (a surrogate or matrix spike) or reagent water or simulated solid matrix (laboratory control sample). Surrogate recovery is reported and is used to assess method performance for each sample analyzed for volatile and semivolatile organic compounds. For organic and inorganic parameters, the stated accuracy objectives apply to spiking levels at or near the midpoint of the calibration curve. For radiochemical analyses, the spiking levels for the control spikes may vary from five to fifty times the method reporting limit.

The calculation formula for percent recovery is:

$$R(\%) = \frac{(C_1 - C_2)(100)}{C_3}$$

Where:

R% = Spike amount recovered

 C_1 = Concentration of analyte in spiked sample

 C_2 = Concentration of analyte in unspiked sample

 C_3 = Concentration of spike added

Acceptance limits are usually based upon established laboratory performance for similar samples. Recoveries outside the established limits may indicate some assignable cause other than normal measurement error and the need for corrective action. This corrective action may include recalibration of the instrument, reanalysis of the quality control sample,

reanalysis of the samples in the batch, re-preparation of samples in the batch, or flagging and qualifying the data as suspect if the problems cannot be resolved. For contaminated samples, recovery of matrix spikes may depend on sample homogeneity, matrix interference, and dilution requirements for quantitation.

Both accuracy and precision are calculated for each batch and the associated sample results must be interpreted by considering these specific measures. The quality assurance objectives for precision and accuracy are to achieve the quality control acceptance criteria specified in the appropriate analytical procedure.

For organic analyses, precision and accuracy are determined by using matrix spike and matrix spike duplicate samples and/or surrogate spike compounds and laboratory control samples.

For inorganic analyses, precision and accuracy are determined by using duplicate samples or matrix spike duplicate samples (precision) and matrix spike and laboratory control samples (accuracy). Samples identified as field blanks cannot be used for duplicate or matrix spike sample analyses.

For radiological analyses, precision and accuracy are determined from the results of duplicate samples or matrix spike duplicate samples (precision), laboratory control sample duplicates (precision) and laboratory control samples (accuracy). Samples identified as field blanks cannot be used for duplicate or matrix spike sample analyses. Percent recovery is the most commonly used measure of accuracy in radiochemistry. The most commonly used measure of precision in radiochemistry is duplicate error ratio (DER).

Quality control limits for accuracy and precision may be developed from intralaboratory historical data or adopted from prescribed limits required by the client. If quality control acceptance criteria do not exist for a given method, then the laboratory may establish

advisory control limits derived from a minimum of four data points. Until verified by a statistically significant data population, the control limits will be considered as advisory limits only and the laboratory will not automatically initiate reanalysis if these limits are not achieved.

Bias describes the systematic error of a measurement process that causes errors in one direction from the true value. Bias results from errors in sampling and/or analytical procedures. Sources of bias include incomplete homogenization before subsampling and incomplete extraction of target analytes. Bias is *not* equivalent to accuracy.

3.4 REPRESENTATIVENESS

Representativeness is a qualitative element. It expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition within a defined spatial and/or temporal boundary.

Sample handling protocols (e.g., holding times, storage, preservation, and transportation) have been developed to preserve the representativeness of the samples. Proper documentation establishes that quality control protocols have been followed and sample identification and integrity ensured. Paragon makes every attempt to ensure that the aliquots taken for analysis are homogeneous and representative of the samples received.

3.5 COMPARABILITY

Comparability is a qualitative expression of the confidence with which one data set can be compared to another. Comparability is achieved by:

 Following established, standardized, and approved sample collection techniques and analytical methods;

- Achieving holding times;
- Reporting results in common units;
- Using consistent detection levels; and
- Reporting data according to consistent rules.

Most organics results are reported in µg/L for water samples and µg/kg for soil samples (exception: petroleum hydrocarbons soil samples and explosives soil samples are reported in mg/kg; TCLP samples are reported in mg/L). Metals results are usually reported in mg/L for water samples and mg/kg for soil samples. Water samples analyzed for miscellaneous water quality parameters are reported in mg/L. Radiological results are usually reported in units of picocuries per liter (pCi/L) or picocuries per gram (pCi/g).

Results for solid samples are usually reported on a dry-weight basis. Results for solid samples analyzed by methods in which the procedure obviates the need for moisture correction are reported on an as-received basis (e.g., explosives by Method SW 8330, tissue, tritium in solids). If moisture determinations have been performed, then percent moisture results are presented on all forms listing analytical results.

3.6 COMPLETENESS

Completeness is an expression of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under normal conditions. Completeness is the percentage of measurements that are judged to be usable (i.e., that meet project-specific requirements). It is expected that the methodology proposed for chemical characterization of the samples collected will provide data that achieve quality control acceptance criteria for 80-95% of all samples collected.

Paragon's objective is 100% completeness for samples unaffected by matrix interferences.

It is recognized that some samples are highly contaminated with target and/or non-target compounds, which necessitate cleanups, multiple analyses, and/or extensive dilutions. As a result of these atypical applications, recoveries and detection limits may be deemed questionable based on internal quality control results.

The equation used to calculate completeness is shown below:

$$C\% = \frac{S}{R} (100)$$

Where:

C = completeness

S = number of successful analyses

R = number of requested analyses

Factors that adversely affect completeness include:

- Receipt of samples in broken containers;
- Receipt of samples in which chain of custody or sample integrity is compromised in some manner;
- Receipt of insufficient volume to perform initial analyses or repeat analyses if initial efforts do not meet QC acceptance criteria;
- Receipt of improperly preserved samples;
- Receipt of samples for which more than 50% of the holding time has expired;
 and
- Receipt of samples that contain high levels of contamination that can cause persistent effects on instrumentation designed for trace-level analyses.

The US EPA has established that there is a 5% probability that the results obtained for any one analyte will exceed the control limits established for the test as a result of random error, assuming the confidence interval is established at 95% (preamble to 40 CFR Part

136, Vol. 49, No. 209, October 26, 1984). As the number of compounds measured increases in a given sample, the probability for realizing statistical error also increases. The number of compounds present in various methods increases the probability that one or more analytes will not meet acceptance criteria to significantly more than the 5% per analyte frequency (e.g., GC/MS Methods SW 8260B and SW 8270C, ICAP Method SW 6010B, and Gamma Spectroscopy Method EPA 901.1). The number of target analytes included in these methods can be used to show that a minimum of four to seven target analytes will exceed the control limits established for these methods as a result of the statistical probability for random error. Establishing quality control criteria that are not consistent with the measurement of the quality objectives for which they are intended should be discouraged.

3.7 METHOD DETECTION LIMIT

The method detection limit (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. The MDL is defined as follows in 40 CFR Part 136 Appendix B:

$$MDL = t_{(n-1, 1-\alpha, = 0.99)} \times \sigma$$

Where:

 σ = Standard deviation of the replicate analyses $t_{(n-1, 1-\alpha, = 0.99)}$ = Student's t-value appropriate to a 99% confidence level

Paragon performs MDL studies for each determinative and preparatory method combination, matrix, instrument, and analytical column. Paragon performs MDL studies annually (or at a frequency prescribed by the method), during method validation, or whenever the basic chemistry of a procedure changes. We analyze an MDL check

standard at approximately twice the calculated MDL value to ensure that the MDL is valid.

Results calculated between the MDL and the method quantitation limit (MQL) contain a significant amount of error (approximately $\pm 100\%$). Therefore, values reported between the MDL and MQL as qualified as estimated. In addition, the calculated MDL value may not be attainable for a given matrix.

An MDL study is not performed for radiological analyses or any components for which spiking solutions are not available or relevant (e.g., pH, ignitability, color, odor, temperature, dissolved oxygen, soil permeability, grain size, etc.). Reporting limits for these kinds of parameters, where applicable, are established based on the laboratory's knowledge of extraction efficiency, instrument sensitivity, and experience with the procedure.

SOP 329 provides additional information about MDL studies.

3.8 METHOD QUANTITATION LIMIT OR METHOD REPORTING LIMIT

Paragon defines a method quantitation limit (MQL) or method reporting limit (MRL) as the analyte concentration at or above which the laboratory's precision and accuracy requirements can be routinely demonstrated and achieved. The statistical error associated with this region of a curve is significantly smaller than that associated with the region near the MDL. The MQL or MRL values for most analytes reported by Paragon are numbers that are approximately 3 to 5 times the values of the MDL for those analytes. It is Paragon's policy to analyze a calibration standard at or below the MQL or MRL when performing an initial calibration. For analyte concentrations measured between the MDL and the MQL or MRL, the laboratory is not able to maintain the precision and accuracy

specified for an analysis technique; therefore, sample concentrations in this range are flagged as being estimated.

3.9 MINIMUM DETECTABLE CONCENTRATION

The minimum detectable concentration (MDC) is used for radiochemical procedures. It is defined as the concentration at which there is a 95% confidence that an analyte signal will be distinguishable from an analyte-free sample.

The general formula for calculating the MDC is based on calculations derived by Currie (Currie, L.A., "Limits for Qualitative Detection and Quantitative Determination," Analytical Chemistry 40(3); pp. 586-693; 1968) and is generally calculated as follows:

$$MDC = \frac{(4.65 X \sigma_b) + 2.73}{T * K}$$

Where:

MDC = Minimum Detectable Concentration

 σ_b = Standard deviation of the measurement background

T = Sample count time

K = Factor incorporating efficiency, abundance, aliquot yield, ingrowth and decay, and activity conversion factors

3.10 TOTAL PROPAGATED UNCERTAINTY

Total propagated uncertainty (TPU) is an estimated measure of "total uncertainty" in a radiochemical result. Various sources of uncertainty associated with the preparation (e.g., aliquot yield) and measurement process (e.g., efficiency, counting uncertainty) are propagated using the law of propagation of uncertainty. The TPU is an integral part of every radiochemical result and is reported as \pm TPU.

SOP 743 provides more information about the calculation and use of TPU.

3.11 SENSITIVITY

The term *Sensitivity* is used in a broad sense to describe the various limits that enable a laboratory to meet project-specific DQOs (e.g., instrument detection limit, method detection limit, method quantitation limit, method reporting limit, contractor required detection limit, contractor required quantitation limit). The instrument detection limit (IDL) is a minimum value that addresses the detection capability of the instrument only. The method detection limit (MDL) is a minimum value that addresses the detection capability for the sample preparation procedures and the instrument. The IDL and MDL values are based on an interference-free matrix that cannot evaluate the effects on sample matrix on the calculated IDL or MDL value. Therefore, calculated IDL and MDL values may not be applicable to environmental matrices.

The method quantitation limit (MQL) or method reporting limit (MRL) is defined as the lowest level that can be reliably measured by a laboratory within defined limits of precision and accuracy. The US EPA CLP SOW uses the terms contractor required detection limit (CRDL) and contractor required quantitation limit (CRQL) to describe a contractually required level of reporting. The *reporting* terms addressed in this paragraph do not describe instrument sensitivity.

3.12 TRACEABILITY

Traceability is the extent to which results can be substantiated by hard-copy documentation, electronic or computer-generated data calculations, computer software, and data generation. Traceability documentation exists in two forms: that which links

final numerical results to authoritative measurement standards and that which explicitly describes the history of each sample from collection to analysis.

See Sections 4, 5, 6, and 9 of this LQAP for additional information about measurement traceability.

3.13 QUALITY ASSURANCE PROJECT PLAN (QAPjP) EXCEPTIONS

As a result of the unknown nature of environmental samples prior to analysis, Paragon has minimal control over analytical and quality control complications that result from *unknown* sample matrix conditions. These conditions may include: highly concentrated samples that contain target compounds of interest and/or non-target components; extremes in sample pH, viscosity, and solubility; and high organic content (both natural and synthetic). Each of these conditions may require a different approach.

Some sample matrices may require the laboratory to employ cleanup and/or dilution techniques in order to analyze the sample by the desired protocol. Unfortunately, diluting a sample necessitates raising reporting limits and often adversely impacts the calculation of surrogate, tracer, and matrix spiking compound recoveries.

Paragon has the responsibility to identify matrix interferences that preclude the generation of "compliant" data. This determination may be made by demonstrating reproducibility (i.e., reanalysis of the affected sample) -- that the quality control measurement failure resulted from sample matrix conditions beyond the control of laboratory -- and not as a result of laboratory error. For example, if the surrogate standard or tracer standard recoveries are outside control limits, then samples are re-extracted and/or re-analyzed. Repeated "non-compliant" results indicate that sample matrix probably prevented the laboratory from reporting results deemed method compliant.

Analytical projects containing particularly "dirty" samples (i.e., highly contaminated with target compounds and/or matrix co-extractives) will often fail to meet pre-established completeness goals (set forth in the QAPjP) when prior site history does not reveal the matrix constituents. Although the laboratory performs all analytical testing and clean up procedures by the prescribed protocols, the results obtained may not meet validation criteria as a result of elevated reporting limits or the frequency at which surrogate, internal, tracer, or matrix spike standard recoveries failed to meet acceptance limits. In cases where the laboratory is unable to meet quality control criteria as a result of sample matrix complications, results that are qualified by data validation guidelines may still be useful to the end user of the data.

Paragon is committed to adhering to method requirements and quality control procedures prescribed by our clients. Paragon will strive to produce compliant data. However, uncertainties associated with environmental samples may preclude the laboratory's ability to generate fully compliant data. Paragon will not assume responsibility for conditions beyond our reasonable control that directly impact the "validity" versus the usability of the associated analytical data generated by the laboratory.

4. SAMPLE PRESERVATION, HOLDING TIMES, AND SAMPLE HANDLING POLICIES

4.1 INTRODUCTION

Defining the magnitude and nature of an environmental problem and developing an appropriate solution requires the collection of representative samples for laboratory analysis and data evaluation. The objective of field sampling is to remove a small portion of an environment that is representative of the entire body. Analytical methods have been standardized but the results of analyses are only as good as the sampling protocol and the sample preservation methods. Defining sampling procedures and the quality elements applicable to environmental testing is beyond the scope of this document and beyond the responsibility of the laboratory.

Although the laboratory is not responsible for sample collection, it is responsible for maintaining the integrity of the sample after receipt. After the sample has been collected, the constituents of the sample must remain as close as possible to the field condition. The length of time that these constituents will remain stable is related to their character and the preservation method used. Preservation is accomplished by the addition of chemical preservatives and/or storage at a controlled temperature. Appendix D lists sample container types, preservation requirements, and holding times.

4.2 FIELD SUPPORT

Paragon provides shipping containers, custody documents, custody seals, pre-cleaned sample bottles, labels, chemical preservatives for water samples, trip blanks, and (upon request) "blue ice" packs to support field-sampling events. Sample kits are prepared at the laboratory to provide the client with all of the sample containers, preservatives, and documentation needed for the analyses required by a project. Paragon typically uses

commercial coolers for the transport of environmental samples from the field to the laboratory. Coolers meet or exceed all protocol requirements (i.e., US DOT, US EPA, ASTM) for shipping.

SOP 205 provides information about preparing bottle orders.

Upon receipt of the field samples at the laboratory, personnel ensure that sample bottles are maintained according to preservation requirements and that sample storage conditions do not contaminate samples. Paragon provides separate storage areas for samples according to the following parameter groups: metals, inorganics, semivolatile organics, volatile organics, fuels, and radiochemical analyses. In addition, Paragon segregates standards, low-level samples, and (known) high-level samples by storing them separately, in dedicated areas. Sample segregation minimizes the possibility of cross-contamination of samples.

4.3 SAMPLE PRESERVATION AND HOLDING TIMES

Paragon provides the required chemical preservatives for water samples and, upon request, "blue ice" packs, for thermal preservation during the shipping process. High quality reagent grade chemical preservatives are added to sample bottles, as needed (see *Form 216*). It is the responsibility of those collecting the samples to properly use these materials and ensure that proper preservation techniques (chilling) are performed and preservative (chemical preservation) requirements are met.

Holding times (usually) begin with the collection of samples and continue until analysis is complete. Holding times for various analyses, matrices, and parameters are presented in *Appendix D*.

4.4 SAMPLE CONTAINERS

Paragon provides pre-cleaned and certified sample bottles for sample collection. Vendor prepared I-Chem 300TM, Eagle Pitcher (level 1) or equivalent bottles are provided. Used sample bottles are never used by the laboratory.

The Sample Control Department maintains certificates of cleanliness that are provided by the vendor for all sample bottles. These certificates are provided to the client upon request. Containers are stored in clean areas to prevent exposure to fuels, solvents, and other contaminants.

4.5 SAMPLE RECEIPT SCHEDULE

Paragon receives samples six days of the week, Monday through Saturday. Paragon requests that clients ship samples for delivery within one day of collection. Shipping containers received at the laboratory on holidays, weekends, or after business hours are placed in the walk-in refrigerator and opened on the next business day unless arrangements are made in advance.

4.6 CHAIN-OF-CUSTODY

Chain-of-custody documentation begins with field sampling and continues through laboratory analysis and disposal. A chain-of-custody record is used to establish an intact, continuous record of the physical possession, storage, and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates. The chain-of-custody record identifies all individuals who handled the sample. Field personnel or client representatives complete a chain-of-custody form for all samples. This form remains with the samples during transport.

Paragon has implemented standard operating procedures (SOPs) to ensure that sample custody objectives of traceability are achieved for every project. See SOP 202 and SOP 318 for information about sample custody and login procedures.

The National Enforcement Investigations Center (NEIC) of EPA defines evidence of custody in the following manner:

- It is in one's actual possession, or
- It is in one's view, after being in one's physical possession, or
- It was in one's possession and then locked or sealed to prevent tampering, or
- It is kept in a secure area, restricted to authorized personnel only.

The sampler should provide the following information on the chain-of-custody form:

- Client project name;
- Project location;
- Field sample number/identification;
- Date and time of sample collection;
- Sample matrix;
- Container type and number of containers for each sample;
- Preservative;
- Analysis requested;
- Sampler signature;
- Signature of person relinquishing samples;
- Date and time relinquished;
- Sampler remarks;
- Custody Seal Number (if applicable); and
- Designation of matrix spike and matrix spike duplicate (MS/MSD) samples.

All transfers of samples except to and from commercial couriers must be recorded on the chain-of-custody form via the "relinquished" and "received by" sections. All information except signatures should be printed.

4.7 SAMPLE ACCEPTANCE POLICY

Paragon's sample acceptance policy requires that a sample meet the following conditions:

- The sample shall be completely documented (sample identification, location, date and time of collection, collector's name, preservation type, sample type, any special remarks concerning the sample);
- The sample shall be identified by a unique identifier using durable labels completed in indelible ink;
- The sample shall be collected in an appropriate container;
- The sample shall be delivered within less than one-half the holding time;
- The sample shall be collected in adequate volume;
- The sample shall not exceed allowed radioactivity levels; and
- The sample shall not show signs of contamination, breakage, or leakage.

Upon receipt of a sample that does not meet the criteria stated above, the Project Manager requests information from the client before proceeding. If the client can provide the information, then data acquired from samples may be reported. Sample receipt discrepancies must be disclosed in the final report and on the Condition of Sample Upon Receipt Form (Form 201).

4.8 SAMPLE RECEIPT PROTOCOLS

Upon arrival of a sample and following initial screen for US Department of Transportation (DOT) compliance and removable radioactivity, sample control personnel inspect the sample and record any discrepancies. Personnel document receipt of all samples in a controlled logbook. *Appendix E* includes a copy of Paragon's Condition of Sample

Upon Receipt Form (Form 201), which provides a checklist of procedures that enables Paragon to document the following:

- Client/Project name;
- Presence/absence of custody seals or tapes of the shipping containers and the condition of the seals (i.e., intact, broken);
- Presence/absence of chain-of-custody (if present, is it complete?);
- Presence/absence of sample tags (if present, are they removable?);
- Agreement/non-agreement between the sample tags, chain-of-custody, and any client documentation;
- Sample temperature;
- Sample condition (intact, broken, leaking);
- Headspace in VOA vials;
- Sample holding time;
- Receipt of adequate sample volume;
- Chemical preservation of sample if required (pH, free chlorine); and
- Completion of radiological screen to ensure compliance with DOT regulations.

Sample temperature is verified upon receipt by measuring the temperature of the temperature blank (if available) or by measuring the temperature of representative samples with an infrared (IR) temperature gun. Samples that require thermal preservation are considered acceptable if the temperature upon arrival is \pm 2°C of the required temperature. An exception to this requirement is made for samples with a specified temperature of 4°C. In this case, a temperature of just above freezing to 6°C is considered acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet the temperature range required. If the sample is packed in ice, then sample control personnel record the temperature on *Form 201* and note that the chilling process has begun.

See SOP 210 for instructions and procedures related to the IR temperature gun.

4.9 SAMPLE LOGIN POLICIES AND PROCEDURES

After completing sample receipt procedures, sample information and analytical requests are entered into the Laboratory Information Management System (LIMS). The following information is entered to produce a work order:

- Client name, contact, address, phone number;
- Date and time of receipt;
- Paragon Work Order number;
- Paragon Project Manager;
- Unique laboratory identifier for each sample;
- Sample description;
- Analyses requested (LIMS calculates holding times for each analysis);
- Special instructions, if applicable; and
- Due date.

In general, a sample delivery group is assigned one work order number in LIMS. Each sample container is assigned a unique identifier that is placed on each container. This unique identification includes all samples, subsamples, and subsequent extracts and/or digestates.

See SOP 201, SOP 202, and SOP 212 for additional information about sample log in, distribution of samples, and LIMS program specifications.

4.10 SAMPLE STORAGE

Samples are stored upon receipt to prevent sample degradation. All refrigerated storage areas are maintained at $(4 \pm 2)^{\circ}$ C. Freezer storage areas are maintained at $(10 - 20)^{\circ}$ C. The temperature of refrigeration units is monitored and recorded twice daily. If the temperature exceeds the prescribed range, then corrective action is taken and documented immediately and the client notified, if appropriate.

Samples are stored away from all standards, reagents, food, and other sources of contamination. Samples are stored in such a manner as to prevent cross contamination. For example, pure product or potentially contaminated samples are tagged as "hazardous" and stored within a secured area, separate from other samples. Waters and soils are generally stored on labeled, separate shelves in secondary containment bins.

See SOP 023 for guidance on secondary containment bins.

Samples designated for radiochemistry analyses <u>only</u> are segregated and most are maintained at ambient temperature. Those samples having suspected activity and scheduled for chemical analyses are segregated and refrigerated.

4.11 SAMPLE ACCESS, DATA ACCESS, AND INTERNAL CHAIN-OF-CUSTODY

It is Paragon's policy that neither samples nor data be released to unauthorized personnel. In order to ensure that this policy is maintained, the laboratory facilities are maintained under controlled access and are restricted to authorized personnel only.

Paragon personnel follow strict internal chain-of-custody procedures to ensure the validity of all data. All samples are signed out in a sample custody logbook when they are removed for analysis. The sample ID, analyst, date, time, and storage location are recorded in the sample custody log or equivalent. Upon return, samples must be signed in (noting analyst, date, time, and storage location).

Paragon's internal chain-of-custody procedures are described in SOP 318.

4.12 SUBCONTRACTING ANALYTICAL SERVICES

Every effort is made to perform analyses within Paragon's laboratory. Should subcontracting be necessary, samples are subcontracted to qualified laboratories -- only after receiving the client's <u>written</u> approval. The specific terms of the subcontract laboratory agreement must include:

- Analytical method required (e.g., SW-846, 40CFR);
- Number and type of samples expected;
- Project specific quality control requirements;
- Deliverables required (hardcopy, electronic);
- Laboratory certification required;
- · Price per analysis; and
- Turn around time requirements.

See SOP 103 for guidance on evaluating a subcontract laboratory's qualifications. See SOP 207 for guidance on submitting samples to a subcontract laboratory.

4.13 SAMPLE DISPOSAL

After completion of sample analysis and submission of the analytical report, unused portions of samples are retained by the laboratory for a minimum of 90 days from date of invoice. Samples will be disposed or returned to the client according to the nature of the samples and the client's specifications. If the sample is to be submitted as evidence in litigation, then disposal of the physical sample occurs only with the concurrence of the affected legal authority, sample data use, and/or submitter of the sample. Paragon documents and retains all conditions of disposal and correspondence between all parties concerning the final disposition of the sample.

Samples, digestates, leachates, extracts, and process waste that are characterized as hazardous, radioactive, or mixed waste are disposed in accordance with federal and state laws and

regulations. Paragon maintains documentation and records demonstrating that all samples, digestates, leachates, extracts, and process waste have been disposed in accordance with all federal, state, and local regulations. This documentation includes: date of disposal; nature of disposal (e.g., sample depleted, sample disposed in hazardous waste facility, sample disposed in mixed waste facility, sample returned to client); and name of the individual responsible for disposal.

4.14 LABORATORY FACILITIES

Appendix F contains a diagram of the Paragon laboratory facility. Paragon maintains constant and consistent test conditions throughout the facility (e.g., temperature, air purification, lighting). All entrances and exits are wired to a laboratory-wide security system that is monitored continuously. Access to the laboratory area from the front offices is restricted by means of keypad locks requiring numeric security code entry. Visitors must sign in at the front desk and must be escorted at all times (some vendors are allowed access without continuous escort, in order to facilitate repairs or deliveries).

SOP 132 addresses issues of building security.

The following paragraphs highlight the areas of the laboratory that are involved with sample receipt, handling, preparation, and analysis of field samples.

4.14.1 SAMPLE RECEIPT AREAS

Paragon's sample receiving area consists of a large dedicated room of more than 500 ft². It contains two fume hoods and radiation survey equipment to safely handle incoming radioactive and mixed waste samples. There is an outside access door to facilitate sample delivery, shipping, and sample kit preparation.

4.14.2 SAMPLE STORAGE AREAS

Paragon's sample receiving area has a walk-in cooler and a freezer that are used for temporary storage of samples. In addition, there are several sample storage locations throughout the laboratory that are used to store samples scheduled for specific analyses. Segregated, refrigerated storage is provided for the following kinds of analyses: organic extractions, volatiles, fuels, wet chemistry, metals, and radiochemistry.

4.14.3 SAMPLE PREPARATION AREAS

The laboratory has six sample preparation/extraction/digestion areas. These areas are divided as follows: four radiochemistry preparation laboratories; one organics extraction laboratory; and one inorganics preparation/digestion laboratory. The total floor space of these six laboratories is approximately 4500 ft².

Laboratory preparation procedures are segregated as much as possible to minimize the potential for contamination, maximize processing efficiency, and maintain analytical integrity. Rigorous cleaning of glassware and apparatus ensures that cross-contamination is minimized. Each laboratory area has a dedicated or locally shared HVAC system that continuously exchanges the laboratory air with filtered and conditioned outside air. There are 34 hoods in the six sample preparation areas and each sample preparation area has at least one hood that is capable of maintaining an average face velocity of 100 feet per minute.

4.14.4 DEIONIZED WATER SYSTEM

Within the laboratory, there are two deionized (DI) water distribution systems available for glassware cleaning, bulk reagent preparation (acid and base solutions and other aqueous reagents), and general use. These DI water systems are monitored and documented to ensure that the water meets specified requirements. DI water is defined as

municipal tap water that has been treated by passing it through a particulate filter, activated carbon unit, cation exchange resin, anion exchange resin, mixed bed resin, and a final "polishing" cartridge. This water contains no detectable heavy metals or inorganic compounds of analytical interest, is relatively free of organic compounds, and meets the requirements specified for ASTM Type II water.

Ultra-pure water, used for equipment blanks and standards preparation, is defined as DI water that has been additionally treated through a Milli-Q (or equivalent) treatment system and contains no organic compounds of analytical interest above Paragon's routine reporting limit. One Milli-Q system is available at the laboratory, and it is capable of continuously delivering water that meets the requirements specified for ASTM Type I water.

See SOP 319 for additional information about DI water systems.

5. ANALYTICAL PROCEDURES

Paragon is capable of analyzing various matrices, including: surface and groundwater, drinking water, soil, sediment, tissue, and waste. Our clients and their regulators select the appropriate promulgated methodologies. Upon request, Paragon develops and validates procedures that are more applicable to a specific objective. *Appendix G* includes a list of Paragon's analytical capabilities.

Analytical procedures are fully described in standard operating procedures (SOPs) that dictate preparation, analysis, review, and reporting of samples. All analytical procedures are conducted in strict adherence with SOPs that have been reviewed and approved by the Technical Manager, the Quality Assurance Manager, and Laboratory Director (or designees). References for analytical procedures are presented in *Appendix B*.

5.1 ANALYTICAL METHODS

Selection of the appropriate method is dependent upon data usage and regulatory requirements. *Appendix B* lists the analytical references routinely used by Paragon. Paragon may modify existing methods in order to:

- Achieve project specific objectives;
- Incorporate modifications or improvements in analytical technology;
- Comply with changing regulations and requirements:
- · Address unusual matrices not covered in available methods, and
- Provide analytical capabilities for an analyte for which there are no promulgated methodologies.

Paragon discloses method modifications to our clients by providing the appropriate SOP for review.

5.2 METHOD COMPLIANCE

5.2.1 **DEFINITION**

Compliance is the proper execution of recognized, documented procedures that are either approved or required. Adherence to these procedures is required in order to provide data acceptable to a regulatory body of competent jurisdiction in a specific regulatory context. Compliance is separate from, but not inconsistent with, technical scientific quality. Paragon accepts compliance as an integral part of the definition of quality. Paragon understands that the expectations of our clients commonly include the assumption that data and reports will satisfy a regulatory purpose and will be found acceptable and compliant with regulatory requirements.

5.2.2 UNDERSTANDING THE REGULATORY FRAMEWORK

Compliance is not likely to be achieved in the absence of an understanding of the regulatory framework. Upon receipt of a statement of work, Paragon attempts to ascertain, prior to accepting samples:

- What regulatory jurisdiction pertains to a project (US EPA, State Department of Health, etc.);
- Within the regulatory jurisdiction, what body of regulations has primacy (RCRA, SDWA, CWA, etc.); and
- Within this context, what QA/QC protocols are required (CLP, DoD QSM, AFCEE, NFESC, USACE, NELAC, etc.).

Paragon works with its clients to achieve a mutual understanding of all requirements. Paragon makes the following commitment to our clients:

- Paragon will proactively attempt to identify and understand the regulatory context of clients' needs.
- Paragon will strive to be expert in understanding and executing the regulatory requirements for compliance.

- Paragon will ensure that we have the capabilities, resources, and facilities to perform the requested analyses;
- Paragon will identify and disclose to clients instances of non-compliance in a forthright and timely fashion.

5.2.3 RESOLVING COMPLIANCE CONTRADICTIONS AND HIERARCHIES

Multiple regulatory jurisdictions may overlap for a specific project, which may cause uncertainty or contradictions to arise in a work plan. Similarly, methods and protocols may be prescribed in a scope of work or QAPjP that either will not achieve stated or implied DQOs or that conflict with the regulatory requirements. Paragon will attempt to detect these inconsistencies and contradictions and will disclose them to clients in a timely fashion. Paragon voluntarily accepts a responsibility to provide information to our clients; however, the primary responsibility for resolving inconsistencies with regulators remains with the client.

5.2.4 DISCLOSURE OF NONCOMPLIANCE

As stated, it is Paragon's policy to disclose in a forthright manner any detected noncompliance that may affect the usability of data produced by Paragon. It is not within our expertise to predict the manner in which a specific regulator or regulatory body will interpret the rules governing analysis; therefore, Paragon is unable to guarantee compliance. It is Paragon's policy that our responsibility begins with a bona fide and competent attempt to evaluate potential compliance issues and ends with disclosure of any findings that may enable our clients to make an informed decision.

SOP 928 provides additional information about policies and procedures for completing nonconformance reports. **Appendix H** includes a copy of Paragon's Nonconformance Form (Form 313).

5.3 NON-STANDARD METHOD VALIDATION

When a non-promulgated method (i.e. methods other than EPA, NIOSH, ASTM, AOAC, etc.) is required for specific projects or analytes of interest or when the laboratory develops a procedure, the laboratory must establish the validity of the method prior to extracting or analyzing a client's samples. Validity is established by meeting criteria for precision and accuracy. Method development and validation must include the following:

- Initial Demonstration of Capability (IDOC) study for every analyst;
- MDL and IDL study for every analyte, matrix, instrument, and column (if applicable);
- validated extraction and analytical criteria; and
- SOP generation and approval.

6. MEASUREMENT TRACEABILITY AND CALIBRATION

6.1 GENERAL REQUIREMENTS

Paragon follows a well-defined calibration routine for all instruments and equipment.

Calibration may be performed by: (1) laboratory personnel using certified reference materials traceable to NIST or equivalent certified materials or by (2) external calibration agencies or equipment manufacturers. The discussion in this section of the LQAP is general in nature because the requirements for calibration are instrument or equipment and method specific.

Details of calibration procedures and requirements can be found in Paragon's standard operating procedures (SOPs), analytical methods, and operations manuals.

6.2 EQUIPMENT LIST

Appendix I of this LQAP lists all major instrumentation available at Paragon. The Quality Assurance Department maintains this list.

6.3 TRACEABILITY OF CALIBRATION

Paragon's program of calibration and/or verification and validation of equipment must ensure that, wherever possible, measurements performed by the laboratory are traceable to national standards of measurement. Paragon requests and maintains calibration certificates that demonstrate traceability to national standards of measurement. If traceability to national standards of measurement is not available or applicable, then Paragon provides evidence of correlation of results (e.g., verifying an in-line resistivity meter by reading the system's output with a conductivity meter; participating in a proficiency testing study).

6.4 REFERENCE STANDARDS OF MEASUREMENT

Paragon uses reference standards of measurement (such as Class S weights or NIST traceable thermometers) for calibration purposes only and these standards are not be available to laboratory personnel. Reference standards of measurement are calibrated or verified annually by a qualified vendor that must provide, where possible, traceability to a national standard of measurement.

Reference standards and measuring and testing equipment may require in-service verifications between annual calibrations and verifications. For example, seven-day temperature wheels are verified quarterly by the Quality Assurance Department to ensure accuracy.

6.5 TRACEABILITY OF STANDARDS, SOLVENTS, AND REAGENTS

Paragon purchases the highest quality standards, solvents, and reagents available. The vendor must supply a Certificate of Analysis or Certificate of Purity (or equivalent) and each department maintains the certificates on file. Each department documents the date of receipt, date opened, and an expiration date for all standards, solvents, and reagents by labeling the original container or the certificate. Each department is responsible for the preparation, documentation, storage, and disposal of its chemicals.

Standards preparation information is recorded in a controlled standards logbook or in a database. The analyst records all information needed to maintain traceability of the standard. Records must indicate the following information for each standard:

- Date of receipt of reference standard;
- Date opened (noted on each bottle);
- Traceability to purchased stock or neat compounds (vendor, lot number);
- Unique internal identification number;

- Date of preparation;
- Name of the analyst;
- Amount of reference material used;
- Final volume;
- Concentration;
- Volume of reagents and solvents used;
- Expiration date of the stock standard and diluted standard.

See SOP 300 and SOP 734 for additional information about standards preparation, storage conditions, and expiration dates of standards.

6.6 GENERAL REQUIREMENTS FOR CALIBRATION

Each calibration is dated and documented to ensure that it is traceable to the method, instrument, date of analysis, analyte, concentration, and response. Sufficient information must be recorded to permit reconstruction of the calibration. Acceptance criteria for calibrations must comply with method requirements.

6.7 INSTRUMENT CALIBRATION

This section defines the essential elements of initial instrument calibration and continuing instrument calibration verification. These procedures ensure that the data will be of known, documented, and appropriate quality for a given application. Initial instrument calibration is used for quantitation and continuing instrument calibration verification is used to confirm the validity of the initial calibration.

6.7.1 INITIAL INSTRUMENT CALIBRATION

The following items are essential elements of initial instrument calibration:

- The details of the initial instrument calibration procedures must be included or referenced in the test method SOP (includes calculations, integrations, statistics).
- Sufficient raw data records must be retained to allow reconstruction of the initial
 instrument calibration (e.g., calibration date, test method, instrument, date of analysis,
 name of analyst, concentration of standards, response, calibration curve, response
 factor).
- Samples must be quantitated from the initial instrument calibration.
- All initial instrument calibration must be verified with a <u>second source</u> standard obtained from a different manufacturer/vendor and traceable to a national standard, when available. If a different manufacturer/vendor is not available, the laboratory must request a different lot number of the standard.
- Criteria for the acceptance of an initial instrument calibration must be established (e.g.,
 RSD, correlation coefficient).
- Exclusion of initial calibration points without technical justification is not allowed (e.g., poor injection or power failure are valid reasons to exclude a calibration point).
- Results of samples outside the known calibration range must be reported as estimated values (i.e., identified by data qualifiers and discussed in the case narrative discussion).
- The lowest calibration standard must be above the detection limit and at or below the method reporting limit (i.e., the method reporting limit must be within the calibration range of the method);
- If the initial instrument calibration results are outside acceptance criteria, then
 corrective action must be performed and the instrument recalibrated before analyzing
 samples. Samples inadvertently analyzed after a failed initial instrument calibration
 must be reanalyzed following an acceptable initial calibration;
- Calibration standards must include concentrations at or below the regulatory limits, if these limits are known to the laboratory.
- The initial calibration range must consist of a minimum of 5 contiguous calibration points for organics analyses and a minimum of 3 contiguous calibration points for

inorganics analyses. If a reference or mandated method does not specify the number of calibration standards, then the minimum number is two, not including blanks or a zero standard.

All reported target analytes and surrogates must be included in the initial calibration.

6.7.2 CONTINUING INSTRUMENT CALIBRATION

There are two kinds of standards that demonstrate the validity of an initial instrument calibration: initial calibration verification standards (ICVs) and continuing calibration verification standards (CCVs).

An ICV is analyzed immediately after the initial calibration and must be successfully completed before analyzing any samples. An ICV is usually prepared from a different source than the initial calibration standards (not required if the CCV is prepared from a different source). The concentration of the ICV must be at or near the middle of the calibration range. Acceptance criteria for an ICV are usually the same as those for a CCV.

When an initial instrument calibration is not performed on the day of analysis, then validity of the initial calibration must be verified with an acceptable CCV prior to sample analysis.

The following items are essential elements of instrument calibration verification and apply to ICVs and CCVs:

- The details of the continuing instrument calibration procedures must be included or referenced in the test method SOP (includes calculations, integrations, statistics).
- Sufficient raw data records must be retained to allow reconstruction of the continuing
 instrument calibration (e.g., calibration date, test method, instrument, date of analysis,
 name of analyst, concentration of standards, response, calibration curve, response
 factor).
- A continuing instrument calibration verification must be repeated at the beginning and end of each analytical sequence. (For GC/MS methods that use an internal standard,

- only one continuing instrument calibration verification must be analyzed <u>before</u> each analytical sequence).
- The concentrations of the calibration verification standards must be varied within the
 established calibration range. At least one of the standards must fall below the middle
 of the calibration range. Paragon usually accomplishes this criterion by analyzing the
 ICV at a different and lower concentration than the CCV.
- Criteria for the acceptance of a continuing instrument calibration must be established (e.g., %D, %Drift from the initial calibration).
- All reported target analytes must be included in the continuing instrument calibration standard.
- If the continuing instrument calibration verification results exceed acceptance criteria,
 then corrective actions must be performed. If routine corrective action procedures do
 not produce a second consecutive calibration verification within acceptance criteria,
 then a new calibration must be performed. Additional sample analysis may not occur
 until a compliant initial calibration curve has been established.

Sample data associated with an unacceptable calibration verification standard may be reported as qualified data for the following reasons:

- When the acceptance criteria for the continuing calibration verification are exceeded
 high (i.e., high bias) and there are associated samples that are non-detects, then those
 non-detects may be reported.
- When the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias), then these sample results may be reported if they exceed a maximum regulatory limit.
- When the acceptance criteria for the continuing calibration verification are exceeded
 high or low and the effect is reproduced by reanalysis (i.e., matrix effects are
 suspected), then the sample results may be reported.

6.8 SUPPORT EQUIPMENT

The requirements in this section apply to all equipment that supports laboratory operations. Support equipment includes: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors) thermal/pressure sample preparation devices, and volumetric dispensing devices (e.g., Eppendorf®, automatic dilutor, automatic dispensing devices). All support equipment must be:

- Maintained in proper working order.
- Calibrated or verified at least annually over the entire range of use, using NIST traceable references when available. The results of said calibration must be documented and within the specifications required of the application for which the equipment is intended.
- Records must be retained to document equipment performance, maintenance, and repair.
- Prior to use on each working day, the following equipment must be verified with NIST traceable references, in the expected use range wherever possible: balances, ovens, refrigerators, freezers, and water baths. Additional monitoring as prescribed by the test method must be performed for any device that is used in a critical test (e.g., water bath).
- Mechanical volumetric dispensing devices (except Class A glassware) must be verified
 for accuracy every month. Glass microliter syringes are considered in the same manner
 as Class A glassware, but a certificate attesting to the syringe's accuracy must be
 provided by the manufacturer and retained by the department.

The following SOPs provide additional information about calibration and verification of support equipment:

- SOP 305: balance calibration and verification;
- SOP 320: monitoring and recording oven temperatures;
- SOP 321: pipet calibration;

- SOP 324: verifying weights;
- SOP 325: monitoring sample cooler temperature with a seven-day recorder;
- SOP 326: monitoring refrigerator and freezer temperature;
- SOP 923: standardization of thermometers; and
- SOP 938: verification of infrared temperature guns.

7. PREVENTIVE MAINTENANCE

The objective of Paragon's preventive maintenance program is to provide a system of instrument care that prevents quality control failures and minimizes lost productivity that results from instrument failure. This program includes a system for documenting all routine and non-routine instrument maintenance and repairs. Analysts maintain calibration and maintenance records of all equipment and instruments that generate analytical data. Paragon maintains service contracts for most major analytical equipment, including: gas and high-performance liquid chromatographs, mass spectrometers, liquid scintillation counters, cold vapor atomic absorption spectrophotometers, inductively coupled plasma spectrophotometers, and balances.

7.1 MAINTENANCE RESPONSIBILITIES

The Department Manager or Technical Manager is responsible for providing technical leadership to all employees who perform analyses. This leadership role includes: (1) serving as a technical resource to help solve equipment and method problems; (2) evaluating and recommending investments in new technologies; (3) improving efficiency; and (4) coordinating instrument repair and maintenance. The Department Manager is further responsible for developing procedures and schedules for maintaining each major instrument or piece of equipment and for delegating specific maintenance responsibilities to employees.

7.2 MAINTENANCE DOCUMENTATION

All routine and non-routine instrument maintenance is documented in maintenance logbooks assigned to each instrument. These maintenance logbooks must include a unique instrument identifier (e.g., serial number). To provide a clear and complete history

of repairs and maintenance associated with each instrument, each entry must include the following elements:

- The reason for the maintenance or repair (e.g., was this action taken to correct a problem or was this action routine instrument maintenance);
- A full description of the maintenance or repair;
- Name of analyst or vendor who performed maintenance or repair;
- Date of maintenance or repair;
- A description of how the analyst demonstrated that the analytical system was
 operating in control after completion of the maintenance or repair and before the
 resumption of sample analysis (only applies if the instrument was taken out of
 service); and
- The initials of the analyst making the entry and date of entry.

7.3 MAINTENANCE SCHEDULES

Preventive maintenance is scheduled and performed on each instrument and piece of equipment in order to minimize downtime and loss of productivity. Other maintenance activities may also be identified as requiring attention on an as-needed basis.

Manufacturers' recommendations and analysts' experience provide the basis for developing maintenance schedules. Contractors and/or employees perform maintenance for several major instruments (e.g., spectrophotometers, gas and liquid chromatographs, analytical balances, etc.).

7.4 SPARE PARTS

An adequate inventory of spare parts is required to minimize equipment downtime. This inventory should include those parts and supplies that:

- Are subject to frequent failure,
- Have limited useful lifetimes, or

Cannot be obtained in a timely manner should failure occur.

Department Managers are responsible for maintaining an adequate inventory of necessary spare parts for all major instruments and equipment items. Examples of spare parts maintained for major instrumentation include: syringes, septa, inserts, columns, tube fittings, filaments, source parts, and traps.

7.5 CONTINGENCY PLAN

In the event of a catastrophic instrument failure, Paragon will make every effort to analyze samples within holding times by alternate means. If the redundancy in instrumentation is insufficient to handle the affected samples, then the Department Manager or Technical Manager notifies the Project Manager immediately. In turn, the Project Manager notifies the client to discuss options that will ensure successful completion of the project.

8. QUALITY CONTROL PROCEDURES

Paragon's quality control (QC) program provides a systematic process that enables the laboratory to evaluate and control the validity of analytical results by: measuring and monitoring the accuracy and precision of each method and matrix; developing control limits; using these limits to detect errors or out-of-control events; and requiring corrective action measures to prevent or minimize the recurrence of these events. Paragon implements QC procedures to ensure that sample data meet the quality objectives of the laboratory and the client.

The purpose of preparing and analyzing QC samples is to demonstrate accuracy and precision of the sample data and efficacy of the method for the target analytes being investigated. Acceptance criteria may be dictated by methods or by project requirements. All assessments of QC data are performed after all rounding and significant figure truncations have been performed.

For all analyses performed by Paragon, the QC samples described in the following section are mandatory. Every determinative SOP contains a table that summarizes the following information: kinds of QC sample, frequency of QC samples, acceptance criteria, and corrective actions required.

8.1 **DEFINITION OF BATCH**

8.1.1 PREPARATION BATCH

A preparation batch consists of as many as 20 field samples of the same or similar matrix that are prepared together by the same analyst(s) within a limited or continuous time period, following the same method, using the same kind of equipment, and same lots of reagents. Each batch must contain the appropriate number and kind of method control QC samples (e.g., MB, LCS) and matrix specific QC samples (e.g., MS/MSD, DUP).

Cleanup procedures may be included as part of the preparation batch. All field and QC samples in the batch should be subjected to the same preparation and cleanup procedures.

8.1.2 ANALYSIS BATCH

The analysis batch (or sequence) consists of samples that are analyzed together within the same or continuous time period(s) on the same instrument and processed against the same calibration. Each analysis sequence must contain the appropriate number and kind of calibration standards and field samples as defined by the method. If samples from a preparation batch are analyzed in multiple analysis batches, the extracted method control and matrix specific QC samples need not be analyzed with every analysis batch.

Some analyses (such as volatile organics by GC or GC/MS, anions by ion chromatography, etc.) require no preparation before analysis; therefore, the preparation batch and analysis sequence are combined.

8.2 PREPARATION BATCH QC SAMPLES AND STANDARDS — DEFINITION AND USE

The results of quality control samples provide an estimate of accuracy and precision for the preparation and analysis steps of sample handling. The following sections describe the QC information provided by each of these analytical measurements.

8.2.1 METHOD BLANK

A method blank (MB) consists of an aliquot of well-characterized, controlled, or certified matrix (e.g., ASTM Type I or II water, sand, solid reference materials, Teflon® chips) that is processed through each sample preparation, cleanup, and analysis procedure. For radiochemical analyses, a suitable blank solid matrix has not been identified; therefore, ASTM Type I or II water is routinely used for the blank matrix for most solid matrices. The volume or weight of the blank must be approximately equal to the sample volume or weight processed. The purpose of the

method blank is to demonstrate that interferences caused by contaminants in solvents, reagents, glassware, and other sample processing hardware are known and minimized. A method blank should not contain target analytes at or above the reporting limit, unless otherwise specified in the method. Sample results are not corrected for blank contamination.

8.2.2 LABORATORY CONTROL SAMPLE

A Laboratory Control Sample (LCS) consists of an aliquot of well characterized, controlled, certified matrix (e.g., ASTM Type I water, sand, solid reference materials, Teflon® chips) that is spiked with analytes of interest and processed through each sample preparation, cleanup, and analysis procedure. The purpose of the LCS is to provide an estimate of bias based on recovery of the compounds from a clean, controlled matrix and to demonstrate that the laboratory is performing the method within accepted guidelines without potential non-matrix interferences.

Where sample pretreatment is not required, such as with ion chromatography, gamma spectroscopy, or GC volatiles in water, the Initial Calibration Verification (ICV) standard or other appropriate control standard may be employed as the LCS. An LCS for methods with extensive lists of analytes that may interfere with one another may include a limited number of analytes, but the analytes included must be representative of as many analytes as is practical.

8.2.3 MATRIX SPIKE/MATRIX SPIKE DUPLICATE

A matrix spike (MS) or matrix spike duplicate (MSD) is a field sample to which known concentrations of target analytes are added before the sample is processed. The purpose of MS/MSD samples is to assess the performance of the method for a particular matrix and to provide information about the sample's homogeneity. Results of the MS/MSD samples are evaluated in relation to the method QC samples to

determine the effect of the matrix in regards to accuracy and precision. Sample results are not corrected for MS/MSD excursions.

To generate the MS/MSD pairs for any analysis, there must be an adequate volume/weight of field sample available. Inadequate sample volumes preclude the possibility of generating this pair of QC samples. Paragon asks clients to designate the sample to be chosen for MS/MSD analysis to ensure that adequate sample volumes are collected.

For some analyses, changing the composition of the sample in any way invalidates the analysis to be performed (e.g., hardness, alkalinity, pH). Therefore, a MS/MSD pair cannot be generated for these analyses. Normally, duplicate sample aliquots are analyzed in order to generate an estimate of a method's precision.

8.2.4 SAMPLE DUPLICATE

A Sample Duplicate (DUP) is a sample that has been split into two portions before the method sample preparation process. It measures sample precision associated with an analysis method from the preparation through final analysis. For organic analyses the MS/MSDs fulfill this function and provide a measure of overall precision.

8.2.5 SURROGATE SPIKES

Surrogates are organic compounds that are similar to the target analytes, but are unlikely to be present in actual field samples. They provide an estimate of bias based on recovery of similar compounds, for a given extraction technique and analysis method combination. These bias estimates incorporate sample matrix effects and field sampling conditions, as well as the variability/bias of the laboratory analysis process. When used in the laboratory, surrogate spikes are introduced into all field and QC samples in a batch, prior to sample preparation. Sample results are not corrected for surrogate recoveries.

8.2.6 CHEMICAL YIELD MONITORS

This analytical tool is used primarily for radiochemical analyses and provides information similar to the surrogate spike discussed above. The primary difference between a chemical yield monitor and a surrogate is that sample results are corrected for chemical yield recoveries and sample results are not corrected for surrogate recoveries. A chemical yield monitor is a substance that has similar chemical characteristics as the parameter being measured. It is introduced into all field and QC samples in a batch during the preparation procedure. Chemical yield monitors also provide information regarding the performance of a method on a sample-by-sample basis.

8.3 CONTROL CHARTS

Control charts are an essential tool that can assist the laboratory in evaluating method control and assessing trends. Control charts can clarify the routine performance expectations for a method and can prevent a measurement system from drifting into an out-of-control situation.

Accuracy control charts are generally maintained for each method that utilizes an LCS. For methods that cannot use LCS samples other acceptance criteria is used to assess method control (e.g., pH, flashpoint, conductivity). If fewer than 20 data points for a method, matrix, and analyte combination are acquired, then control charts yield scant information.

8.3.1 ACCURACY CONTROL CHARTS

Accuracy (or recovery) control charts are evaluated by plotting the individual percent recovery point for an analyte on a control chart and comparing its value against the current control limits. If the spike recovery values for the current analytical batch meets the acceptance criteria for that method, then the data point (and batch) are accepted. Paragon's LIMS calculates and updates the control limits for each of the control analytes.

Control chart limits are calculated from the recovery values from all data processed. The upper and lower warning limits of the control chart are values equal to the average recovery plus or minus two times the standard deviation (95% confidence interval). The upper and lower control limits of the control chart are values equal to the average recovery plus or minus three times the standard deviation (99% confidence interval). These four limits, the average recovery, standard deviation, minimum value, maximum value, and population are displayed on the control chart.

The frequency of updating control limits may vary for different methods. The Quality Assurance Department reviews control charts quarterly and updates control limits as needed. Intralaboratory historical control limits are generally not updated more than once per year.

8.3.2 OUTLIER REJECTION

For the generation of control charts and other quality control data that monitor the laboratory's performance, it is essential to prevent spurious or erroneous data from being incorporated. It may be necessary to reject data as an outlier to prevent an adverse effect on the values being calculated. In every case, the cause of the outlier rejection must be clearly understood and the Quality Assurance Manager must be informed of and agree to the manual rejection of any data point.

For the purposes of statistically determining whether a data point is an outlier or not,
Paragon may use the procedures discussed in the Dixon Rank Sum Test or the Grubbs
Test. If a data point is determined to be an outlier, then it will be identified as an outlier
(with a flag or notation). An outlier is not incorporated into the database when updating limits.

8.4 SECOND COLUMN OR SECOND DETECTOR CONFIRMATION PROCEDURES

Second column or detector confirmation is performed for several GC and HPLC techniques. Whenever two dissimilar chromatography columns or two detectors of a different nature are available for a given method, the laboratory performs second column or second detector confirmation analysis to confirm the identity of target analytes in field samples. When second column analysis is performed for any chromatography technique, the following policies apply:

- Every attempt will be made to calibrate the second (confirmatory) column in the same manner as the quantitative (primary) column. The same initial and continuing calibration standards will be analyzed on the confirmation column in the same manner as the quantitation column. The purpose of this dual calibration requirement is to allow the possibility of reporting quantitative results from the confirmation column if interferences on the primary column prevent target analyte quantitation.
- For chromatographic techniques, the determination of target analytes in a sample depends solely on peak retention times observed in both primary and secondary chromatograms. If target analyte peaks are present at the proper retention times in both confirmation and quantitation chromatograms and both values are above the reporting limits, then Paragon determines this analyte to be confirmed. If either chromatogram has target analyte peaks that are below the reporting limit for that parameter, a value of "less than" the reporting limit is reported by the laboratory.
- In general, Paragon reports the highest value of the two columns, per SW 8000B guidance, for the following methods: EPA 504.1, SW 8011, EPA 505, SW 8081, EPA 608, SW 8082, SW 8141, EPA 614, SW 8151, EPA 515.1, EPA 615, SW 8021, and EPA 602.
- Paragon reports the value from the primary column for Methods SW 8330 and SW 8332. Co-elutions or interferences are frequently observed on the secondary column for these HPLC methods.

Paragon reports the value from the primary detector and wavelength (254 nm) for
 Methods SW 8310 and EPA 610. Co-elutions or interferences are frequently
 observed on the second wavelength or detector for these HPLC methods. In addition,
 the second wavelength or detector does not detect all compounds.

8.5 MANUAL RE-INTEGRATION POLICIES AND PROCEDURES

Many data collection systems allow the analyst to reprocess data, thereby allowing for the manual re-integration of analyte peaks. Paragon makes every attempt to optimize peak integration parameters; however, manual reprocessing of data must be performed to correct a data system's integration error (e.g., missed peak assignment, incorrect peak assignment, over-integration of area, under-integration of area). Manual re-integrations may *not* be performed to meet initial or continuing calibration criteria or any QC criteria (e.g., tuning criteria, surrogate recovery, spiking compound recovery). Calibration and QC criteria must be achieved by recalibration of the instrument.

Whenever a manual integration is performed, the analyst performing this process must include a hardcopy of the original and re-integrated peak in the final report. In addition, the analyst must sign and date the re-integrated page and document the reason for re-integration on the printout. The re-integration must be documented in the case narrative. See SOP 939 for additional information about manual re-integration policies and procedures.

9. DATA REDUCTION, VALIDATION, AND REPORTING

Data transfer and reduction are essential functions in summarizing information to support conclusions. It is essential that these processes are performed accurately and are followed by multiple reviews before data are submitted to a client. All analytical data generated by Paragon are extensively reviewed for accuracy and completeness. The data validation process consists of data generation, reduction, and three levels of review, as described below.

9.1 CORRECTION OF ERRORS IN DOCUMENTS

During the course of processing and reviewing sample analysis results, it may be necessary to correct documentation errors. To maintain the integrity of the documentation generated by the laboratory, changes to documentation must be made in the following manner:

- A single line must be struck through the error so that the original text remains legible;
- A corrected entry must be made adjacent to the error; and
- The person making the change must initial and date the entry.

If corrections are made in computerized data, Paragon's LIMS provides an electronic audit trail of the original entry and correction.

SOP 303 provides additional information about correcting errors.

9.2 DATA REDUCTION

Paragon's analysts perform data reduction. This process consists of interpreting results and verifying calculated concentrations in samples from the raw data. The complexity of the data reduction is dependent on the specific analytical method and the number of discrete operations involved in obtaining a measurement (e.g., digestions, dilutions, cleanups, or concentrations). The analyst calculates the final reportable values from raw data or enters all necessary raw data into the LIMS so that the LIMS can calculate the final reportable values.

Data are reduced according to protocols described in SOPs and method-specific review checklists. Computer software used for data reduction is validated before use and verified regularly by manual calculations. All information used in calculations is recorded in order to facilitate reconstruction of the final results (e.g., raw data, calibration files, tuning records, results of standard additions, interference check results, sample response, and blank or background-correction protocols). Information about the preparation of the samples is maintained in order to facilitate reconstruction of the final results (e.g., weight or volume, percent weight for solids, extract volume, dilution factor).

Copies of all raw data and the calculations used to generate the final results, as recorded in hardbound laboratory notebooks, spreadsheets, electronic data files and LIMS record files are retained in the project file to allow reconstruction of the data reduction process.

9.3 DOCUMENTATION OF RAW DATA

All manual documentation of raw data is performed on appropriate forms or in notebooks. All notebooks are bound and have pre-numbered pages. All data are recorded directly, promptly, and legibly in indelible ink. Entries may not be obliterated by erasure, overwriting files, or correction fluid.

There are several minimum requirements that apply to all raw data documents. At a minimum, all raw data must display the following information:

- The date when the process was performed;
- The name of the staff member who performed the process;
- Identity of all samples or standard solutions that were processed; and
- The methodology used to process the samples.

9.4 DATA REVIEW

The analyst who generates the analytical data has the primary responsibility for the correctness and completeness of the data. This initial review step, performed by the analyst, is designated *Level 1 Review*. All data are generated and reduced following protocols specified in laboratory SOPs and method-specific checklists. The analyst reviews the data to ensure that:

- Sample preparation information is correct and complete;
- Analysis information is correct and complete;
- The appropriate SOPs have been followed;
- Analytical results are correct, complete, and compliant with program specifications;
- Calculations, conversions, and data transfers are accurate;
- QC samples meet criteria for accuracy and precision;
- Special sample preparation and analytical requirements have been met; and
- Documentation is complete (e.g., all anomalies in the preparation and analysis are documented; all manual re-integrations are signed and dated, "before and after" plots submitted, and manual re-integrations are noted in the case narrative, in general; noncompliance reports are complete, etc.).

Following completion of Level 1 Review, the analyst then forwards the data to a second reviewer. Level 2 Review is performed by a Department Manager or another qualified

reviewer whose function is to provide an independent review of the data. This review is structured to ensure that:

- Calibration data are scientifically sound, appropriate to the method, and completely documented;
- QC samples are within established guidelines;
- Qualitative identification of target analytes is correct;
- Quantitative results are correct;
- Documentation is complete and correct (e.g., anomalies in the preparation and analysis have been documented, noncompliance reports are complete, etc.); and
- The data are ready to be incorporated into the final report.

Level 2 Review ensures that all calibration data and QC sample results are reviewed, and the analytical results from selected samples are verified to the bench sheet. If no errors are detected, then the review is considered complete. If any problems are found, then additional samples are verified to the bench sheet. The process continues until no errors are found or until the data package has been reviewed in its entirety. Level 2 Review is documented and the signature of the reviewer and the date of review are recorded. The reviewed data are then approved for release and a final report is prepared.

Finally, a Project Manager performs a *Level 3 Review* of the data package. The intent of this review is to verify that the report is complete and that the data meet the overall objectives of the project.

As part of Paragon's quality assurance program, the Quality Assurance Department performs an additional review of 10% of all data packages for technical completeness and accuracy. This review occurs after invoice. The Quality Assurance Department compiles a quarterly report of these reviews and notifies the Department Manager if systematic trends are discerned.

Each step of this review process involves evaluation of data quality based on both the results of the QC data and the professional judgment of those conducting the review. This application of technical knowledge and experience to the evaluation of the data is essential in ensuring that data produced are consistently of known, documented, and appropriate quality.

9.5 DATA REPORTING

Reports contain final results, methods of analysis, level of detection, and QC data. For solid samples, sample values are routinely reported in units of dry weight measure. In addition, analytical problems, and/or any modifications of referenced methods are noted in the case narrative. The number of significant figures reported in a result is consistent with the limits of uncertainty (reported to two significant figures) inherent in the analytical method. Consequently, most analytical results are reported to no more than two or three significant figures.

Standard units for radiochemical analyses relate to the level of activity of the sample per unit volume or weight. Typical units for these radioactivity measurements are:

- Picocuries per gram or picocuries per liter (pCi/g or pCi/L); or
- Disintegrations per minute per gram or disintegrations per minute per liter (dpm/g or dpm/L); or
- Becquerels per gram or Becquerels per liter (Bq/g or Bq/L), where 1 Curie = 2.22
 * 10¹² dpm and 1 Curie = 3.7 * 10¹⁰ Bq.

Standard units for inorganic analysis are units of mass per unit of weight or unit of volume. Typical units for these inorganic measurements are:

 Milligrams per liter or micrograms per liter (mg/L or μg/L) for metals results in aqueous samples and milligrams per kilogram (mg/kg) for metals in solid matrices;

- Wet chemistry parameters (such as hardness, total organic carbon, total organic halides, total cyanide, etc.) are reported in units of milligrams per liter (mg/L) for aqueous matrices and milligrams per kilogram (mg/kg) for solid matrices; and
- Miscellaneous parameters (such as pH, specific conductivity, flashpoint, etc.) have specific reporting units mandated by their respective analysis technique.

Standard units for organic analysis are units of mass per unit of weight or unit of volume.

Typical units for these organic measurements are:

- For total petroleum hydrocarbons (gasoline and/or diesel), usual reported units of measure are milligrams per liter (mg/L) for aqueous matrices and milligrams per kilogram (mg/kg) for solid matrices;
- For PCBs, usual reported units of measure are milligrams per kilogram (mg/kg) for oil matrices;
- For high explosives, usual reported units of measure are milligrams per kilogram (mg/kg) for solid matrices;
- For TCLP parameters, usual reported units are milligrams per liter (mg/L); and
- For all other parameters, the reporting units for these analyses are micrograms per liter (μg/L) or micrograms per kilogram (μg/kg).

9.5.1 FACSIMILE REPORTS

For projects that require rapid turnaround of sample analysis results, the laboratory may provide a facsimile to the client, followed by the full data report at a later date. If the analysis results provided by facsimile have undergone the same review processes followed for final data packages, then the fax report indicates that the sample analysis results are final. However, if the accelerated turnaround time requirements preclude a full review/validation of the sample data, then the report is stamped "PRELIMINARY" to indicate that results may change as the review process is completed.

9.5.2 ELECTRONIC DATA DELIVERABLES

The electronic data deliverables (EDDs) generated by the laboratory are project-specific and are produced in a format specified by the client. Information presented in corresponding fields of the hardcopy report and EDD are identical as both are generated from the LIMS. Before submitting the EDD file, the Project Manager or designee verifies that the EDD is complete and meets the client's format requirements. All EDDs are submitted to the client on diskettes or transmitted electronically.

9.5.3 HARDCOPY DATA PACKAGES

The format and content of a data report is dependent upon project specifications, and it is beyond the scope of this document to describe project-specific report requirements. In the absence of client-specified data package deliverables, the following sections describe the items that must be included in all reports.

9.5.3.1 COVER LETTER

The cover letter is presented in block letter style and includes:

- The date the report was prepared;
- Paragon's name and address, name of contact person, and telephone number;
- The client's name and address:
- A tabular presentation of field/client sample ID, Paragon Sample ID, date received, matrix and date collected (presented as an attachment, known as the Sample Cross Reference Table);
- A list of each analysis performed and total number of pages for each analytical report;
- Identification of all test data provided by a subcontractor;
- A discussion of previously submitted or partial reports that pertain to the samples discussed in the current report; and
- The signature of Paragon's Project Manager or designee.

9.5.3.2 REPORT FORMAT

Analysis reports are presented in tabular format, and consistent significant figures and units of measurement are used. The following information is included in each report:

- Laboratory name, client name, project name or number (if one exists);
- Paragon sample ID and client/field sample ID (if different);
- Dates of receipt of sample, date and time of sample collection, time of sample preparation and/or analysis;
- Sample matrix;
- Identification of whether data are calculated on a dry weight or wet weight basis;
- Identification of the reporting units;
- Parameters analyzed (method reference), results, units of measurement, and reporting limits;
- Case narrative that identifies test method, describes any deviation from method or contractual requirements, additions or exceptions to SOP, and discloses any conditions that may affect the quality of the results;
- Identification of results for any sample that did not meet sample acceptance requirements;
- Footnotes or qualifiers referenced to specific data (if required);
- Explanations or keys to flags and abbreviations used;
- Surrogate and tracer recoveries, where applicable;
- Identification of numerical results with values below the reporting limit;
- When required, a statement of the estimated uncertainty of the test result; and
- A signature and title, or equivalent electronic identification of the personnel who accept responsibility for the content of the report and the date of issue.

If a report is reissued, the amendments must clearly state that the report is reissued. The cover letter and case narrative must describe why the report has been reissued and which sample results have been reissued.

9.5.3.3 QUALITY CONTROL REPORT

Each final report includes a QC report that summarizes results from the associated laboratory control sample, method blank, and matrix QC samples. Additional QC samples may be prepared and reported to comply with project-specific requirements.

9.6 DATA QUALIFIERS - FLAGGING CODES

Whenever the data quality objectives of this LQAP are not met, the associated sample results must be flagged with the appropriate flagging codes. These codes are applied only in the event that the laboratory cannot generate (through reanalysis) fully compliant data. If sample values are reported outside the calibration range of the method or unresolvable interferences exist in the sample, then descriptive codes are applied to the result.

Data qualifiers are added by the laboratory prior to reporting the analysis results. The laboratory appends data qualifiers to each environmental field sample, based on an evaluation of all available QC information (e.g., ambient blanks, equipment blanks, trip blanks, field duplicates, matrix spike/matrix spike duplicate samples, laboratory blanks, laboratory control samples, calibration verification standards, etc.). Analytical batch comments are added to the narrative section of each data report to explain any non-conformance or other issues.

9.7 RECORDS AND DATA STORAGE

Records provide the direct evidence and support for the necessary technical interpretations, judgments, and discussion concerning laboratory results. These records, particularly those that are anticipated to be used as evidentiary data, provide the historical evidence needed for later review and analyses. Records must be legible, identifiable, and retrievable. They must be protected against damage, deterioration, fire, theft, vermin, and loss. Paragon retains all records for a minimum of seven (7) years.

Laboratory records include the following kinds of documentation:

- Bound notebooks with pre-numbered pages;
- Personnel qualification, experience, and training records;
- Administrative records;
- Quality assurance records (e.g., retired SOPs, PT results, internal and external audit reports and responses, retired LQAPs;
- Equipment maintenance records.
- Calibration records;
- Traceability of standards, solvents, and reagents;
- Sample management records (e.g., sample preservation; sample container; sample identification; sample identification, receipt, acceptance or rejection, and log in);
- Sample storage and tracking (e.g., shipping documents, transmittal forms, internal chain of custody records);
- Disposal of samples, subsamples, digestates, leachates, contact waste and name of responsible party;
- Chain-of-custody forms; sample analysis request forms;
- Final reports (e.g., cover letter, sample control documents, all raw data, sample and quality control forms, manual and automated calculations, confirmatory analyses, review checklists);
- Correspondence between Paragon and the client;
- Original data (raw data and calculated results);
- Standard operating procedures; and
- Analytical change request forms.

Upon completion of a work order, project reports are scanned to create image files. The reports are scanned to a dedicated server that is backed up daily. In addition, files are backed up nightly to the IS Manager's computer. These reports are segregated by month

and work order. After all reports have been scanned for a particular month, they are burned to two (2) identical compact disks (CDs). One CD remains on site and the other is stored offsite in a bank vault. This procedure has been used since January 2001 and provides five (5) copies of a project report.

Prior to electronic storage, Paragon created paper copies of project reports. Paragon's record storage contractor maintains an inventory of all files that Paragon stores at the contractor's facility. The contractor is responsible for the maintenance and protection of those records. Upon request, the contractor retrieves records and delivers them to the laboratory on the next business day.

As of this writing, no provisions have been made to destroy any records generated by Paragon. Should Paragon destroy any records, written notification will be provided to all clients affected. If a specific contractual requirement or government regulation requires that records be maintained for a longer period of time, then project files will be marked and retained as required.

In the event that the laboratory goes out of business or transfers ownership, Paragon will inform our clients in writing of this business decision and will transfer records at the client's request.

9.8 REVIEW, REVISION, AND DISTRIBUTION OF QUALITY ASSURANCE DOCUMENTS

Every employee must review the LQAP upon hire and annually thereafter. The Quality Assurance Manager bears primary responsibility for revising the LQAP and ensuring that it meets industry standards. The LQAP is reviewed and approved by the following personnel: the Laboratory Director; the Quality Assurance Manager; and every

Department Manager and Technical Manager. Following approval, the laboratory implements the revised LQAP.

The Quality Assurance Department distributes the LQAP as a controlled document to employees and maintains distribution records. The Quality Assurance Department retains the original document. If a client, regulator, or auditor requests a copy of the LQAP, then the Quality Assurance Department distributes the LQAP as a controlled or uncontrolled document, per the request.

Every employee must review assigned SOPs upon hire and annually thereafter. Assigned personnel (usually a Department Manager) update SOPs as necessary. SOPs are reviewed and approved by the following personnel: a Technical Manager (or other staff member knowledgeable in the technical processes described by the SOP); the Quality Assurance Manager; and the Laboratory Director. Following approval, the document is released for implementation in the laboratory. A list of contents of current SOPs is provided in *Appendix J*.

The Quality Assurance Department distributes SOPs as controlled documents to employees and maintains distribution records. If a client, regulator, or auditor requests a copy of an SOP, then the Quality Assurance Department distributes the SOP as a controlled or uncontrolled document, per the request.

The Quality Assurance Department retains the original SOPs and provides two complete copies of all SOPs, which are placed in designated locations in the laboratory. Selected SOPs are provided to each department. The laboratory copies are printed on specially marked paper that indicates the controlled nature of these documents. Laboratory personnel may only refer to <u>controlled</u> SOPs while performing procedures.

SOP 926 and SOP 929 provide additional guidance on the review, revision, and distribution of controlled documents.

Project-specific QAPjPs are distributed to the Project Manager, Technical Manager, and/or Quality Assurance Manager by the client. In general, the Project Manager reviews and summarizes the QAPjP via LIMS Project Specifications and only distributes the QAPjP upon request.

9.9 PROCEDURES FOR HANDLING UNACCEPTABLE DATA

All QC information is recorded in the notebooks and printouts in the same format used for sample results. It is the analyst's responsibility to evaluate the quality control sample data against prescribed limits. When an analysis of a QC sample (method blank, laboratory control sample, calibration verification standard, etc.) demonstrates that the associated samples are not in control, the analyst must immediately notify the Department Manager. The Department Manager consults the Quality Assurance Manager and/or Project Manager to determine whether the analysis can proceed, or if selected samples should be re-extracted and/or re-analyzed, or if specific corrective action needs to be taken before analyzing additional samples. All noncompliant analyses must be documented. The analyst or Department Manager completes a Non-Conformance Report NCR Form (Form 313) for out-of-control events that require documentation. If non-compliant data cannot be corrected, then affected results must be flagged as discussed above, the discrepancy disclosed in the case narrative, and the NCR Form included in the report.

See SOP 928 for additional information about Non-Conformance Reports.

9.10 COMPLAINTS

If a complaint or any circumstance raises doubt concerning Paragon's compliance with its policies or procedures or with the requirement of a method or quality system, the laboratory must document the complaint and resolution on Form 313, the NCR Form. Paragon will respond to all complaints in a timely fashion and will retain the documentation.

9.11 CONFIDENTIALITY

All laboratory results and associated raw data are confidential and may not be released to or discussed with any party other than the client who requested the analytical services. Access to laboratory records and LIMS is limited to laboratory personnel. Records are available for an accrediting authority's on-site review. Paragon expects that auditors will honor our clients' and Paragon's confidentiality requirements and will not discuss any results, documents, or records viewed during the course of an audit.

10. AUDITS

10.1 INTERNAL AUDITS

Two kinds of internal audit procedures are used to assess and document performance of laboratory staff: internal audits and proficiency testing standards. These are performed at specified intervals under the direction of the Quality Assurance Department. These audits form one of the bases for corrective action requirements and constitute a permanent record of the conformance of measurement systems to quality assurance requirements.

10.1.1 INTERNAL TECHNICAL AND SYSTEMS AUDITS

Internal audits include both technical and systems audits and provide an overview of laboratory operations. At least 12 internal audits must be performed annually. In addition, Paragon performs an annual systems audit of the entire laboratory to verify compliance with the requirements of Paragon's quality assurance program and policies and the NELAC standard.

The auditor uses a checklist to perform the internal audit. A checklist is designed to enable the auditor to ensure that all areas of laboratory operations are reviewed and to enable the auditor to record findings and observations promptly. The scope of internal audits may include the examination of the operations of a specific analytical department or may focus on the evaluation of a specific quality-related system as applied throughout the laboratory.

Examples of system-wide elements that may be audited include:

 Standard operating procedures, including system of review, issue, filing, maintenance, training, understanding, documentation of deviations and implementation of SOPs;

- Adherence to standard operating procedures, the LQAP, and regulations;
- Personnel and training files, including job descriptions, resumes, documented training and training file maintenance;
- General laboratory safety, including appropriate clothing, waste disposal, health and safety plan review, obvious safety concerns;
- Labeling of reagents, solutions, standards, and associated documentation;
- Equipment and instrumentation documentation, calibration;
- Maintenance records, operating manuals;
- Sample handling, storage and disposal including storage locations, security,
 tracking/chain-of-custody, disposal practices and records, labeling and retention;
- Documentation of sample analysis, methodologies, quality control requirements;
- Documentation of discrepancy reports and corrective action;
- General procedures for data security, review, documentation, reporting and archiving; and
- Laboratory logbook documentation and review.

When the operations of a specific department are evaluated, several functions may be reviewed, such as:

- Documentation of technical training and analyst proficiency;
- Method detection limit studies:
- Internal chain-of-custody documentation;
- Nonconformance documentation;
- Documentation of standard preparations;
- Instrument maintenance documentation:
- Standard operating procedures;
- Documentation of sample preparation and analysis; and
- Documentation of data review.

Audit results are reported in writing to Department Managers for review and corrective action, if necessary. The original copy of the completed report, with responses, is maintained by the Quality Assurance Department.

See SOP 937 for additional information about internal audit procedures.

10.1.2 PROFICIENCY TESTING STUDIES

Paragon contracts vendors to provide proficiency testing (PT) standards. These kinds of studies enable Paragon to demonstrate competency for continued accreditation, to demonstrate competency in a newly developed method, or to demonstrate effective corrective action. The results of these standards are evaluated by the Quality Assurance Department. Deficiencies in the laboratory's performance will be addressed and a corrective action developed and documented by the Department Manager.

Paragon participates in the following interlaboratory proficiency testing studies:

- US Department of Energy (US DOE), Office of Environmental Management
 (OEM), Quality Assessment Program (QAP) -- twice annually.
- Environmental Resource Associates, Radiochemistry Studies -- twice annually.
- US Department of Energy (US DOE), Idaho Operations Office, Mixed Analyte
 Performance Evaluation Program (MAPEP) -- twice annually.
- Water Pollution Study (WP) -- twice annually.
- Water Supply Study (WS) -- twice annually.
- Soil Study -- twice annually.

Participation in these programs enables Paragon to monitor its data quality throughout the year. These programs require the laboratory to perform analyses for various methodologies (SW-846, SDWA, CWA, ASTM), matrices, and analytes. Analyte lists includes: semivolatile organics, volatile organics, organochlorine pesticides,

polychlorinated biphenyls, organophosphorous pesticides, phenoxyacid herbicides, petroleum hydrocarbons, metals, minerals, nutrients, and radionuclides.

Analyses of PT standards are conducted in-house, in the manner prescribed by the provider, and within the turnaround time stipulated. PT standards are disseminated to the laboratory and processed by qualified analysts who routinely perform the analysis type.

10.2 MANAGERIAL REVIEW

Paragon performs an annual review of its quality system and its testing and calibration activities to ensure the effectiveness of the quality system and to introduce changes if necessary. The review may include:

- Input from Department Managers;
- An assessment of internal audits:
- An assessment of external audits;
- Results of proficiency testing studies;
- Results of quarterly QA Department reports (NCRs, HTVs, data review);
- An assessment of turnaround times (TATs);
- An assessment of training performed:
- Changes in the volume and kind of work accepted:
- Feedback from clients; and
- An assessment of corrective actions.

The Quality Assurance Department maintains records of the review.

10.3 EXTERNAL AUDITS

External audits may be performed by a state or federal agency or client as part of an ongoing certification process, or as a result of Paragon's participation in specific programs/projects that require an external laboratory audit to be performed. External laboratory audits may include reviews of analytical capabilities and procedures, chain-of-custody procedures, document control, quality systems, and quality control procedures. External audits may include analysis of blind PT samples. Should Paragon drop or lose an accreditation, the Project Manager must notify all clients that may be affected.

See Appendix K for a list of Paragon's state and federal certifications.

11. CORRECTIVE ACTIONS

11.1 INTRODUCTION

Corrective action is necessary when any measurement system fails to follow this LQAP, the appropriate SOP, project-specific instructions, or whenever an error is detected. Items that may need corrective action range from a minor problem such as an analyst failing to sign a form to a major problem such as an analyst using an improper analytical method. In general, items needing corrective action fall into two categories: short-term and long-term, each requiring different action.

Short-term Corrective Actions: These actions address minor and major problems that can be corrected immediately. Examples include failure to date or sign a form and errors in data entry. Corrective action is initiated by verbally calling attention to the problem followed by written notification, if warranted.

Long-Term Corrective Actions: These actions address minor and major problems that require a series of actions to resolve the problem. The actions to be taken are coordinated by the Department Manager or Quality Assurance Manager and a Non-Conformance Report Form (Form 313, Appendix H) or another form is used to document the action.

The Non-Conformance Report Form describes: the client, work order, method, samples, analyst, description of non-conformance, probable cause (if known), the corrective action measure(s) taken, and the final disposition/resolution of the data. The form is signed and dated by the analyst, Department Manager, Project Manager, and Quality Assurance Manager. See SOP 928 for additional information about reporting non-conformances.

11.2 RESPONSIBILITIES FOR CORRECTIVE ACTION

When an out-of-control event is recognized, each employee involved with the analysis in question has an interactive role and responsibility. It is the responsibility of the employee who causes or detects the non-conformance to initiate a corrective action, usually by completing Form 313.

11.2.1 ANALYST

The initial responsibility to monitor the quality of a function or analytical system belongs to the individual performing the task or test. Quality indicators are evaluated against laboratory established or project-specific QA/QC requirements. If the evaluation reveals that any of the QC acceptance criteria are not met, then the analyst must immediately correct the problem. When an acceptable resolution cannot be achieved and/or data quality is negatively impacted, the analyst notifies the Project Manager and Department Manager and completes Form 313 immediately.

11.2.2 DEPARTMENT MANAGER OR TECHNICAL MANAGER

The Department Manager or Technical Manager reviews all analytical and QC data for reasonableness, accuracy, and clerical errors. If a non-conformance is detected that cannot be corrected, then the Department Manager completes Form 313 immediately and works with the analyst, Project Manager, and Quality Assurance Manager to document the non-conformance thoroughly and report the qualified data correctly.

11.2.3 PROJECT MANAGER

The Project Manager reviews results, events, and proposed corrective actions for reasonableness and correlation to the project requirements. If a non-conformance affects

the quality of the data, the Project Manager notifies the client immediately to discuss options.

11.2.4 QUALITY ASSURANCE MANAGER

If a non-conformance occurs that is unnoticed at the bench or supervisory level (e.g., a failure on a PT standard), the Quality Assurance Manager notifies the Department Manager via a corrective action request. The Department Manager investigates the non-conformance, develops a corrective action, and forwards the documentation of corrective action to the Quality Assurance Manager.

12. PERSONNEL TRAINING

The selection of well-qualified personnel is a factor that contributes to Paragon's success. Therefore, qualifications of personnel are based upon education and experience. In order to maintain qualified staff and to provide personnel advancement within the laboratory, Paragon follows a formal documented program of orientation and training.

12.1 ORIENTATION

Before working in the laboratory, new employees receive a four-part orientation: a human resources orientation, a quality assurance orientation, a health and safety and radiation safety orientation, and a department orientation. The human resources orientation involves matters of immediate personal concern such as benefits, salary, and company policies. The quality assurance orientation addresses topics related to ethical conduct; responsibilities and authorities of the Quality Assurance Department; quality assurance document hierarchy (i.e., LOAP, SOPs, QAPiPs); and good laboratory practices. The health and safety and radiation safety orientation provides an in-depth examination of Paragon's Chemical Hygiene Plan and safety program, which are consistent with the requirements of OSHA's Hazard Communication Program (29 CFR Part 1910.1200); Paragon's Radiation Protection Plan: Paragon's Emergency and Contingency Plan, and Paragon's Waste Management Plan. The department orientation focuses on the new employee's basic understanding of the role of operations within the structure of Paragon. The departmental training emphasizes the employee's scientific background and work experience to provide the employee with a level of competence so that the individual will be able to function within the defined responsibilities of his/her position immediately.

Temporary employees receive the same orientation as regular staff with the exception of the human resources orientation.

See SOP 143 for additional information about quality assurance orientation and training for new employees.

12.2 ANALYTICAL TRAINING

Analysts/technicians are qualified to perform specific analytical procedures and methods. The qualification process, at a minimum, typically consists of background/theory, a documentation of on the job training, and a demonstration of proficiency. Additional training may include: lectures; programmed learning; conferences and seminars; specialized training by instrument manufacturers; and participation in proficiency standard programs. Department Managers are responsible for providing documentation of analytical training and proficiency for each employee in their group. The Quality Assurance Department maintains a training file for each technical employee.

12.2.1 INITIAL DEMONSTATION OF CAPABILITY

New analysts and technicians are trained by Department Managers or Technical Managers according to the following guidelines:

- The new employee observes an analytical procedure in which the analytical method is
 demonstrated by trained personnel. Job requirements are outlined and quality control
 measurements are defined. A copy of the method and the SOP is given to the
 employee for him/her to review prior to beginning the analysis.
- For most methods, the trainee performs an Initial Demonstration of Capability (IDOC) by preparing and/or analyzing four (4) blank spike samples under the supervision of the Department Manager or Technical Manager or an analyst proficient in that method. Results or preparation and/or analysis are evaluated and problems or corrective actions discussed. If the blank spike recovery and precision data meet quality control criteria for that method, the technician or analyst is deemed to have demonstrated proficiency and is allowed to work on actual client samples. If values are outside current acceptance limits, then training continues until the trainee can

consistently meet the acceptance criteria for the method. After the certification process has been successfully completed, the Department Manager forward the documentation to the Quality Assurance Department for inclusion into the employee's training file.

12.2.2 CONTINUING DEMONSTRATION OF CAPABILITY

Paragon's personnel are required to demonstrate their proficiency upon hire and annually thereafter for the methods they perform. The annual Continuing Demonstration of Capability (CDOC) may be demonstrated by performing another IDOC or as described below.

12.2.2.1 METHOD DETECTION LIMIT (MDL) STUDIES

Many analytical methods require the periodic generation of MDL data. The generation of acceptable MDL values requires a thorough understanding of the total analytical process and is a rigorous test of the proficiency of the analytical staff that performs this analysis. An analyst's or technician's performance in an MDL study (that generates method detection limit values that are consistent with past performance) may be used to demonstrate initial and/or continuing proficiency in a method. This information may be used in lieu of other demonstrations of proficiency, except when a regulatory promulgated method explicitly requires specific procedures to be followed for the initial demonstration of proficiency.

12.2.2.2 PROFICIENCY TESTING STANDARDS

As stated in Section 10 of this LQAP, Paragon participates in several proficiency testing programs. These programs typically submit single-blind standards to the laboratory and return a performance summary after results have been furnished to the sponsoring agency. Successful participation in these programs by personnel is a rigorous demonstration of the staff's ability to perform routine analytical procedures. Paragon considers 90% to be a minimum acceptable score for each analytical procedure. Records of successful participation in these programs may be used to demonstrate that an employee has been

adequately trained in the methods that he/she performs. This information may be used in lieu of other demonstrations of proficiency, except when a regulatory promulgated method explicitly requires specific procedures to be followed for the initial demonstration of capability.

12.3 TRAINING RECORDS

Training records for all employees are maintained by the Quality Assurance Department. Training files may contain (but are not limited to) the following information and are initiated by the departments indicated in the table below.

Responsible Departmens	Description of Training Record
Quality Assurance	signed Code of Ethics
	transcript or diploma
	resume
	personnel qualifications form
	signature on file
	qa training
	annual ethics training
	LQAP training
	PT standard results
	MDL study results
	off-site training certificate
Health and Safety	health and safety training documentation and test results
	radiation safety training documentation and test results
	off-site training certificate
Operations	IDOC/CDOC training documentation
	SOP/method training

14. GLOSSARY, ACRONYMS, AND SYMBOLS

14.1 GLOSSARY

TERM

DEFINITION

Absorption:

1. The process by which on substance is taken into the body of another substance. 2. The penetration of molecules or ions of one or more substances (gas, liquid, solid) into the interior of another substance. (NIRP Classes)

substance. (NIRP Glossary)

Acceptance criteria:

Specified limits placed on characteristics of an item, process, or

service defined in requirement documents. (ASQC)

Accreditation:

The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (NELAC)

Accrediting Authority:

The territorial, State, or Federal Agency having responsibility and accountability for environmental laboratory accreditation and which

grants accreditation. (NELAC)

Accuracy:

The degree of agreement between an observed value and the accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations. (QAMS)

Adsorption:

The process by which a gas, vapor dissolved material, or very small particle adheres to the surface of a solid due to chemical or physical

forces. (NIRP Glossary)

Aliquot:

A discrete, measured, representative portion of a sample taken for

analysis. (EPA QAD)

Ambient:

Usual or natural surrounding conditions, e.g. ambient temperature – the natural, uninfluenced temperature of the surroundings. (NIRP

Glossary)

Analyst:

The designated individual who performs the "hands-on" analytical

methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality. (NELAC)

Analyte:

The specific chemicals or components for which a sample is analyzed; may be a group of chemicals that belong to the same chemical family and that are analyzed together. (DoD QSM)

Analytical Detection Limit:

The smallest amount of an analyte that can be distinguished in a sample by a given measurement procedure throughout a given (e.g. 0.95) confidence interval. (Applicable only to radiochemistry). (DoD QSM)

Analytical reagent grade:

Designation for the high purity of certain chemical reagents and solvents given by the American Chemical Society. (DoD QSM)

Assessment:

The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of NELAC). (NELAC)

Assessment Criteria:

The measures established by NELAC and applied in establishing the extent to which an applicant is in conformance with NELAC requirements. (NELAC)

Assessor:

One who performs on-site assessments of accrediting authorities and laboratories capability for meeting NELAC requirements by examining the records and other physical evidence for each one of the tests for which accreditation had been requested. (NELAC)

ASTM Type I Water

Reagent water with a conductivity of less than 0.06 umho/cm or a resistivity greater than or equal to 16.7 MΩcm at 25°C and has been polished with a 0.45 um membrane filter. For additional specifications refer to ASTM S1193-77, "Standard Specification for Reagent Water." (DOE QSM)

ASTM Type II Water

Deionized water with a conductivity of less than 1.0 umho/cm or a resistivity greater than or equal to 1.0 MΩcm at 25°C. For additional specifications, refer to ASTM S1193-77, "Standard Specification for Reagent Water." (DOE QSM)

Atomization:

A process in which a sample is converted to free atoms. (DoD QSM)

Audit:

A systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity. (EPA-QAD)

Background:

Ambient signal response recorded by measuring instruments that is independent of radioactivity contributed by the radionuclides being measured in the sample. (DOE QSM)

Batch:

Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one to twenty environmental samples of the same NELAC-defined matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group. An **analytical batch** can include prepared samples originating from various environmental matrices and can exceed 20 samples. (NELAC Quality Systems Committee)

Bias:

The deviation of a single measured value of a random variable from a corresponding expected value, or a fixed mean deviation from the expected value that remains constant over replicated measurements within the statistical precision of the measurement (Synonyms: deterministic error, fixed error, systematic error). (DOE QSM)

Blank:

A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, or analysis. The blank is subjected to the same analytical and measurement process as the associated samples. Blanks include:

Equipment blank: a sample of analyte free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)

Field blank: a blank prepared in the field by filling a clean container with pure deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)

Trip blank: Contaminant free water, or appropriate matrix, which accompanies bottles and samples during shipment to assess the potential for sample contamination during shipment. Trip blanks are not opened in the field, and are required for Volatile Organic

Analysis only. (NIRP)

Instrument Blank: A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Method blank: a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all the steps of the analytical procedures. (NELAC)

Reagent blank: a sample consisting of reagent(s), without the target analyte(s) or sample matrix, introduced into the analytical procedure at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps. (QAMS)

Blind Sample:

A sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample, but not the composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process. (NELAC)

Calibration:

To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements. See Initial Calibration. (NELAC)

Calibration Check (Initial Calibration Verification):

Verification of the ratio of instrument response to analyte amount, a calibration check is done by analyzing for analyte standards in an appropriate solvent. Calibration check solutions are made from a stock solution which is different from the stock used to prepare calibration standards. (NIRP Glossary)

Calibration curve:

The graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (NELAC)

Calibration Method:

A defined technical procedure for performing a calibration. (NELAC)

Calibration Standard:

A substance or reference material used to calibrate an instrument

(QAMS)

Carriers:

Carriers are typically non-radioactive (e.g. natural strontium, barium, yttrium) elements. The follow similar chemical reactions as the analyte during processing and are added to samples to determine the overall chemical yield for the analytical preparation steps. The yield of the carrier is determined gravimetrically or by ICP. (DOE QSM)

Certified Reference Material

A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body. (ISO Guide 30 - 2.2)

Chain of Custody form:

Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers, the mode of collection, preservation, and requested samples. (NELAC)

Chemical:

Amy element, compound, or mixture of elements and/or compounds. Frequently, chemical substances are classified by the CAS rules of nomenclature for the purposed of identification for a hazard evaluation. (DoD OSM)

Chemical Carrier (Yield)

See Carrier

Chemical Yield (Recovery):

The fraction of target analyte carried through a radiochemical separation or purification process. This value is used to correct radiochemical results for acceptable losses occurring during the preparation process. See Carrier.

Clean Air Act:

Passed in 1970 as amendments to 42 USC 7401, and was amended in 1990. Its purpose is to "protect and enhance the quality of the Nation's air resources". Its primary application is through Prevention of Significant Deterioration permits to regulate new potentially polluting facilities. Of increasing importance are the National Emission Standards for Hazardous Air Pollutants (NESHAPs). (NIRP)

Clean Water Act:

Passed in 1977 as an amendment to the Federal Water Pollution Control Act first passed in 1956. It's objective is to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." The Act's major enforcement tool is the National Pollutant discharge Elimination System (NPDES) permit. (NIRP)

Client (DoD):

The party that has agreed to pay the bill for services rendered by the laboratory, and with whom the laboratory has a contractual relationship for that project. For a laboratory, this is typically the prime contractor who originally hires the laboratory for the project. and who signs the contract as the receiver of services and resulting data. In cases where the laboratory has a direct contractual relationship with DoD, the client shall be the Government's authorized contracting officer. The contracting officer, as the client, shall consult with the Government's authorized technical representative when dealing with laboratory technical issues. It is understood that typically other "Clients" are present at other levels of the project, but they may be removed from the day-to-day decision-making (for example, installation representatives, service center representatives, various other Government officials). Specific circumstances may require the direct notification of these other clients, in addition to the prime contractor or DoD representative; these circumstances shall be included as part of specific project requirements. (DoD QSM)

Code of Federal Regulations(CFR):

The basic reference source for Federal rules. Published annually, it is a compilation of the regulations of various federal agencies. The CFR is divided into 50 titles according to subject. For example, Title 7 deals with agriculture, Title 40 with the environment, and title 49 with transportation. Titles are divided into chapters, then to parts, sections, etc. The section is the basic unit of the CFR. Ideally, it consists of a short, concise presentation of a single point. It is important to note that CFR's are changed by publication of the Federal Register (FR). The CFR's are the combination of regulations published in the FR for the previous year. (NIRP Glossary)

Combined Standard Uncertainty (Total Propagated Uncertainty:

An estimate or approximation of the error associated with a measured value by propagation of individual uncertainties. See Total Propagated Uncertainty. DOE QSM

Comparability:

A qualitative parameter expressing the confidence with which one data set can be compared to another. Comparable data are produced through the use of standardized procedures and techniques.

Completeness:

Measure of the amount of valid data obtained from a measurement

system compared to the amount that was expected to be obtained under correct normal conditions. The equation for completeness is:

% Completeness = $\frac{\text{# of valid data points obtained}}{\text{# of data points expected}} \times 100$

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) The Federal statute enacted in 1980 and amended in 1986 that establishes a comprehensive, statutory framework for identifying, investigating, and cleaning up releases of hazardous substances to the environment.

Compound:

A unique combination of chemical elements, existing in combination to form a single chemical entity. (DoD QSM)

Component:

A single chemical entity, such as an element or compound. Multiple components may compose one analyte. (DoD QSM)

Compromised Samples:

Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situations require analysis, the results must be appropriately qualified. (NELAC)

Confidential Business Information (CBI):

Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. NELAC and its representatives agree to safeguarding identified CBI and to maintain information identified as such in full confidentiality. (NELAC)

Confirmation:

Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to: second column calibration, alternate wavelength, derivatization, mass spectral interpretation, alternative detectors, or additional cleanup procedures. (NELAC)

Conformance:

An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.

(ANSI/ASQC E4-1994)

Congener:

A member of a class of related chemical compounds (e.g. PCB's,

PCDD's). (DoD QSM)

Consensus Standards:

A protocol established by a recognized authority. (DoD QSM)

Continuing Calibration:

The process of analyzing standards periodically to verify the

maintenance of calibration of the analytical system.

Contract Required Detection Limit

Minimum level of detection acceptable under the contract Statement of Work. (NIRP Glossary)

(CRDL):

Contributor:

A participant in NELAC who is not a Voting Member.

Contributors include representatives of laboratories, manufacturers, industry, business, consumers, academia, laboratory associations, laboratory accreditation associations, counties, municipalities, and other political subdivisions, other federal and state officials not engaged in environmental activities, and other persons who are interested in the objectives and activities of NELAC. (NELAC)

{Art III, Const}

Control Chart:

A graphical plot of test results with respect to time or sequence of measurement, together with limits within which they are expected

to lie when the system is in a state of statistical control.

Control Limit:

A range within which specified measurement results must fall to signify compliance. Control limits may be mandatory, requiring corrective action if exceeded, or advisory, requiring that

nonconforming data be investigated and flagged.

Corrective action:

The action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to

prevent recurrence. (ISO 8402)

Counting efficiency:

The ratio of the net count rate of a radionuclide standard source to

its corresponding known activity. (DOE QSM)

Counting Uncertainty (Poissonian):

A statistical estimate of uncertainty in a radiochemical measurement due to the random nature of decay. Every radiochemical result is reported with an associated counting

uncertainty, usually at the 95% confidence interval.

Curies:

The traditional unit used to express the activity (amount) of

radioactive material. The SI unit for the activity is the bequerel. See Units. (DOE QSM)

Daily Reliability Check

A periodic check of the Continuing Calibration of an instrument used for radiochemical measurements.

Data audit:

A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e. that they meet specified acceptance criteria). (ISO 8402)

Data Quality Objectives:

The qualitative or quantitative statements that specify the quality of data required to support decision for any process requiring chemical or physical analysis.

Data reduction:

The process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (EPA-QAD)

Daughter:

A nuclide formed by radioactive decay of a parent radionuclide.

Deficiency:

An unauthorized deviation from acceptable procedures or practices, or a defect in an item. (ASQC)

Definitive Data:

Data that are generated using rigorous analytical methods, such as approved EPA reference methods. Data are analyte specific, with confirmation of analyte identity and concentration. Methods produce tangible raw data in the form of paper printouts or electronic files. Data shall satisfy QA/QC requirements. For data to be definitive, either analytical or total measurement error shall be determined and documented. (Data Quality Objectives for

Superfund)

Demonstration of Capability:

A procedure to establish the ability of the analyst to generate acceptable accuracy. (NELAC)

Desorption:

The release of chemicals attached to solid surfaces. (NIRP Glossary)

Desorption Efficiency:

The mass of target analyte recovered from sampling media, usually a sorbent tube, divided by the mass of target analyte spiked on to the sampling media expressed as a percentage. Sample target masses are usually adjusted for the desorption efficiency. (NELAC)

Detection Limit: The lowest concentration or amount of the target analyte that can be

identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See Method Detection

Limit. (NELAC)

Digestion: A process in which a sample is treated (usually in conjunction with

heat) to convert the sample into a more easily measured form.

(DoD QSM)

Dilution Factor: The factor by which the dilution level of the sample differs from

that of a predefined method blank. The method blank is prepared within the prescribed parameters of the method, and has a dilution factor of one. The dilution factor does not include a dryness factor.

(DOE QSM)

Document Control: The act of ensuring that documents (and revisions thereto) are

proposed, reviewed for accuracy, approved for release by

authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed

activity is performed. (ASQC)

Dry Weight: The weight of a sample based on percent solids. The weight after

drying in an oven at 105 °C.

Duplicate Analysis: The analyses or measurements of the variable of interest performed

identically on two sub samples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling,

preservation, or storage internal to the laboratory. (EPA-QAD)

Duplicate (Replicate) Error Ratio (DER/RER): A measure of precision used to assess agreement between radiochemical duplicates (replicates) that compares the discrepancy between two measurements to the associated

uncertainties.

Duplicate Sample:

A second aliquot of the same sample that is treated the same as the original sample in order to determine the precision of the method.

Electronic Data
Deliverable (edd):

The electronic media prescribed by the requirements set forth in the

Deliverable (edd): statement of work, (DOE QSM)

Eluent: A solvent used to carry the components of a mixture through a

stationary phase. (DoD QSM)

Elute: To extract; specifically, to remove adsorbed material from an

adsorbent by means of a solvent. (DoD QSM)

Elution:

A process in which solutes are washed through a stationary phase

by the movement of a mobile phase. (DoD QSM)

Energy Calibration:

The correlation of the multichannel analyzer (MCA) channel number to decay energy, obtained from the location of peaks from

known radioactive standards. (DOE OSM)

Environmental

Program:

An organized effort that assesses environmental concerns and leads to the collection of data, either in the field or through laboratory

analysis. (DoD QSM)

Equipment Blank:

Special type of field blank used primarily as a check on equipment decontamination procedures. Laboratory deionized water is passed over sampling equipment after decontamination.

False Negative:

An analyte incorrectly reported as absent from the sample, resulting in potential risks from their presence. (DoD QSM)

False Positive:

An item incorrectly identified as present in the sample, resulting in a high reporting value for the analyte of concern. (DoD QSM)

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA): The enabling legislation under 7 U.S.C. 135 et seq., as amended, that empowers the EPA to register insecticides, fungicides, and

rodenticides. (NELAC)

Federal Water Pollution Control

Act:

See Clean Water Act

Field Blank:

A sample prepared in the field by adding ASTM Type II water to a clean sample container. The field blank is used to indicate the presence of contamination due to sample collection and handling. See Blank. (DOE QSM)

Field of Accreditation:

NELAC's approach to accrediting laboratories by matrix, technology/method and analyte/analyte group. Laboratories requesting for a matrix-technology/method-analyte/analyte group combination or for an updated/improved method are required to submit only that portion of the accreditation process not previously

addressed. (NELAC section 1.8ff)

Field of Proficiency

NELAC's approach to offering proficiency testing by matrix,

Testing:

technology, and analyte/analyte group. (NELAC)

Field Sample:

A portion of material received by the laboratory to be analyzed, that is contained in single or multiple containers and identified by a unique field ID number.

Finding:

An assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition. (NELAC)

Governmental Laboratory:

A laboratory owned by a Federal, state, or tribal government; includes government-owned contractor-operated laboratories. (NELAC)

Half Life (T 1/2):

The time required for 50% of a radioactive isotope to decay. (DOE OSM)

Holding Time (Maximum Allowable Holding The maximum times that samples may be held prior to analysis and still be considered valid or not compromised. (40 CFR Part 136)

Homogeneity:

Times):

The degree to which a property or substance is evenly distributed throughout a material.

Homologue:

One in a series of organic compounds in which each successive member has one more chemical group in its molecule than the next preceding member. For instance, CH₃OH (Methanol), C₂H₅OH (Ethanol), C₃H₇OH (Propanol), C₄H₉OH (Butanol), etc., form a homologous series. (DoD QSM)

Initial Calibration:

The process of analyzing standards, prepared at specified concentrations, to define the quantitative response, linearity and dynamic range of the instrument to the analytes of interest. Initial calibration is performed whenever the results of a continuing calibration do not conform to the requirements of the method in use or at a frequency specified in the method. See Calibration.

Inspection:

An activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic. (ANSI/ASQC E4-1994)

Instrument

The concentration of an analyte that produces an output signal twice

Detection Limit (IDL):

the root mean square of the background noise, or the parameter determined by multiplying by three the standard deviation obtained of three to five times the desired IDL on three nonconsecutive days with seven consecutive measurements per day. An IDL is only required for metals analysis. (DOE QSM)

Interference, Spectral:

Occurs when particulate matter from the atomization scatters the incident radiation from the source or when the absorption or emission of an interfering species either overlaps or is so close to the analyte wavelength that resolution becomes impossible. (DoD OSM)

Interference, chemical:

Results from the various chemical processes that occur during atomization and later the absorption characteristics of the analyte. (DoD QSM)

Interim Accreditation:

Temporary accreditation status for a laboratory that has met all accreditation criteria except for a pending on-site assessment, which has been delayed for reasons beyond the control of the laboratory. (NELAC)

Internal Standards:

A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method. (NELAC)

Isomer:

Generally, any two chemicals with the same chemical formula but with a different structure. (DoD QSM)

Isotope:

A variation of an element that has the same atomic number of protons but a different weight because of the number of neutrons. Various isotopes of the same elements may have different radioactive behaviors, some are highly unstable. (NIRP Glossary)

Key Peak:

A spectral peak used for identification or quantitation of an isotope. (DOE QSM)

Key Staff:

At a minimum, the following managerial and supervisory staff (however named) – executive staff (for example, Chief Executive Officer, Chief Operating Officer, laboratory director, technical director); technical directors/supervisors (for example, section supervisor for organics and inorganics); quality assurance systems directors/supervisors (for example, QA officer, quality auditors); and support systems directors/supervisors (for example, information systems supervisor, purchasing director, project manager). (DoD QSM)

Laboratory:

A body that calibrates and/or tests. (ISO 25)

Laboratory Control Sample (LCS):

(However named, also Laboratory Fortified Blank, Blank Spike, or QC Check Sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias, or to assess the performance of all or a portion of the measurement system. (NELAC)

Laboratory Duplicate:

Aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently. (NELAC)

Legal Chain of Custody Protocols:

Procedures employed to record the possession of samples from the time of sampling until analysis, and are performed at the special request of the client. In addition to routine documentation of collection, transport, and receipt of samples, these protocols document all handling of the samples within the laboratory. (NELAC)

LIMS

Laboratory Information Management System (LIMS) that is used to schedule and track work orders and report hardcopy and electronic data.

Lot:

A quantity of bulk material of similar composition processed or manufactured at the same time.

Manager (however named):

The individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual. (NELAC)

Matrix:

The substrate of a test sample.

Field of Accreditation Matrix: these matrix definitions shall be used when accrediting a laboratory (see Field of Accreditation):

Drinking Water: any aqueous sample that has been designated a potable or potential potable water source.

Non-Potable water: any aqueous sample excluded from the definition of Drinking Water matrix. Includes surface water,

groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

Solid and Chemical Materials: includes soils, sediments, sludges, products, and by-products of an industrial process that results in a matrix not previously defined.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

Quality Systems Matrix: These matrix definitions are an expansion of the field of accreditation matrices and shall be used for purposes of batch and quality control requirements. These matrix distinctions shall be used:

Aqueous: any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

Drinking Water: any aqueous sample that has been designated a potable or potentially potable water source.

Saline/Estuarine: any aqueous sample from an ocean or estuary, or other salt-water source such as the Great Salt Lake.

Non-aqueous Liquid: any organic liquid with <15% settleable solids.

Biological Tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: includes soils, sediments, sludges, and other matrices with > 15% settleable solids.

Chemical Waste: a product or by-product of an industrial process that results in a matrix not previously defined.

Air and Emissions: whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device. (NELAC)

Matrix Spike (spiked sample or fortified sample):

A sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency. (OAMS)

Matrix Spike
Duplicate (spiked sample or fortified sample):

A second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte. (QAMS)

May:

Denotes permitted action, but not required action. (NELAC)

Method:

See Test Method.

Method Blank:

A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. (NELAC)

Acceptable levels of contamination are defined by project specific data quality objectives. See Blank.

Method Detection Limit:

The Method Detection Limit (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero. It may be determined using replicate spike samples prepared by the lab and taken through all steps of the method. The detection limit is calculated using the appropriate student's t-parameter times the standard deviation of a series of spiked samples. (Ref. 40 CFR Part 136, Appx. B)

Minimum Detectable Activity (MDA, Lower Limit of Detection): The minimum detectable activity is the smallest amount (activity or mass) of an analyte in a sample that will be detected with a probability beta of nondetection (Type II error) while accepting the probability alpha of erroneously deciding that a positive (non-zero) quantity of analyte is present in an appropriate blank sample

(Type I error). For the purposes of this standard, the alpha and beta probabilities are both set at 0.05 unless otherwise specified. (ANSI N 13.30 and ANSI N42.23)

Minimum Detectable Concentration:

The Minimum Detectable Activity expressed in concentration units.

Must:

Denotes a requirement that must be met. (NELAC)

National Institute of Standards and Technology (NIST):

An agency of the U.S. Department of Commerce's Technology Administration that is working with the EPA, States, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested States can be accredited by NIST to provide NIST traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater. (NIST)

National
Environmental
Laboratory
Accreditation
Conference NELAC)

A voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP. (NELAC)

National
Environmental
Laboratory
Accreditation
Program (NELAP)

The overall program of which NELAC is a part. (NELAC)

National Voluntary Laboratory Accreditation Program: A program administered by NIST that is used by providers of proficiency testing to gain accreditation for all compounds/matrices for which NVLAP accreditation is available, and for which the provider intends to provide NELAP PT samples. (NELAC)

Negative Control:

Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (NELAC)

NELAC Standards:

The plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the National Laboratory Accreditation Conference. (NELAC)

NELAP Recognition:

The determination by the NELAP Director that an accrediting authority meets the requirements of the NELAP and is authorized to

grant NELAP accreditation to laboratories. (NELAC)

Nonconformance:

An indication or judgement that a product or service has not met the requirements of the relevant specifications, contract or regulation, also the state of failing to meet the requirements. (DoD QSM)

Non-governmental Laboratory:

Any laboratory not meeting the definition of the governmental laboratory. (NELAC)

Objective Evidence:

Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measures, or tests that can be verified. (ASQC)

Performance Audit:

The routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory. (NELAC)

Performance Based Measurement System (PBMS): A set of processes wherein the data quality needs, mandates, or limitations of a program or project are specified and serve as criteria for selecting measurement processes which will meet those needs in a cost effective manner. (NELAC)

Positive Control:

Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects. (NELAC)

Practical Quantitation Limit (PQL):

The lowest concentration where the 95% confidence interval is within 20% of the true concentration of the sample. The percent uncertainty at the 95% confidence level shall not exceed 20% of the results for concentrations greater than the practical quantitation limit. (DOE QSM)

Precision:

The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms. (NELAC)

Preservation:

Refrigeration and/or reagents added at the time of sample collection (or later) to maintain the chemical and/or biological integrity of the sample. NELAC)

Primary Accrediting

The agency or department designated at the Territory, State, or

Authority:

Federal level as the recognized authority with responsibility and accountability for granting NELAC accreditation for a specified field of testing. (NELAC) [1.5.2.3]

Proficiency Testing (PT):

A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (NELAC) [2.1]

Proficiency Testing Program:

The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all the participating laboratories. (NELAC)

Proficiency Testing Study Provider:

Any person, private party, or government entity that meets stringent criteria to produce and distribute NELAC PT samples, evaluate study results against published performance criteria and report the results to the laboratories, primary accrediting authorities, PTOB/PTPA, and NELAP. (NELAC)

Proficiency Test Sample: A sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (QAMS)

Protocol:

A detailed written procedure for field and/or laboratory operation (e.g. sampling, analysis) that must be strictly followed. (EPA-QAD)

Pure Reagent Water:

Shall be water (defined by national or international standard) in which no target analytes or interferences are detected as required by the analytical method. (NELAC)

Qualitative:

Analysis without regard to quantity or specific numeric values. (NIRP Glossary)

Quality Assurance:

An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (QAMS)

Quality Assurance Project Plan:

A Quality Assurance Project Plan (QAPjP) is a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific are to be achieved. (EPA-QAD)

Quality Control:

The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it

meets the needs of the users. (QAMS)

Quality Control Sample:

An uncontaminated sample matrix spiked with known amounts of analytes from a source independent from the calibration standards. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. (FRA CAR)

the measurement system. (EPA-QAD)

Quality Manual:

A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (NELAC)

Quality System:

A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

(ANSI/ASQC E-41994)

Quantitation Limits

Levels, concentrations, or quantities of a target variable (e.g. target analyte) that can be reported at a specified degree of confidence. (NELAC) The value at which an instrument can accurately measure an analyte at a specific concentration (i.e. a specific numeric concentration can be quantified). These points are established by the upper and lower limits of the calibration range. (DoD clarification)

Quantitative:

Analysis with regard to quantities or specific numeric values.

(NIRP Glossary)

Radioactive Decay:

The process by which a spontaneous change in nuclear state takes place. This process is accompanied by the emission of energy

and subatomic particles. (DOE QSM)

Radiation Yield:

The amount of radiation of the type being measured that is produced per each disintegration, which occurs. For gamma

spectrometry, this is commonly called gamma abundance. (DOE QSM)

Radionuclide Tracer:

A traceable internal standard, usually a unique isotope of the element being determined, added to each sample in known amount which enables quantitation of analytes of interest independent of external means of calibration.

Range:

The difference between the minimum and the maximum of a set of values. (EPA-QAD)

Raw data:

Any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm, or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g. tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be

submitted. (EPA-QAD)

Record Retention:

The systematic collection, indexing, and storing of documented information under secure conditions. (EPA-QAD)

Reference material:

A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning valued to materials. (ISO Guide 30-2.1)

Reference Method:

A method of known and documented accuracy and precision issued by an organization recognized as competent to do so. (NELAC)

Reference Standard:

A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived. (VIM-6.08)

Region of Interest (ROI):

In radiochemical analysis, the Multichannel Analyzer region defining the isotope of interest displayed in terms of energy or channels. (DOE OSM)

Relative Bias:

The quotient of the bias divided by the expected value. (DOE QSM)

Relative Percent Difference:

A measure of precision between two duplicate (replicate) results expressed as the percent difference between the results relative to the average of the results.

Replicate Analyses:

The measurements of the variable of interest performed identically on two or more sub-samples of the same samples within a short time interval. (NELAC)

Replicate Samples:

A second, separate sample collected at the same time, from the same place, for the same analysis, as the original sample in order to determine overall precision.

Reporting Delivery Group:

Up to 20 field samples collected at one site, under one task order, or geographical area received within each 14 calendar day period (7-calendar day period for statement of work requiring 14-day deliverables). The 14-day period begins with the receipt of the last sample received by the laboratory. Samples may be assigned to the last appropriate reporting delivery group by matrix (i.e. all soils in one reporting delivery group, all wastes in another). Data for all samples in a reporting delivery group must be submitted together in one package. In the event that the reporting delivery group is defined in the statement of work, the requirements of the statement of work will supersede this definition of the reporting delivery group. (DOE QSM)

Reporting Limit:

The level at which method, permit, regulatory and client specific objectives are met. The reporting limit may never be lower than the statistically determined MDL, but may be higher based on any of the above considerations. Reporting limits are corrected for sample amounts, including the dry weight of solids, unless otherwise specified.

Required Detection Limit (RDL):

A contractually specified detection limit that, under typical analytical circumstances, should be achievable (synonymous with contract required detection limit). (DOE QSM)

Required Reporting Limit (RRL):

A contractually defined numeric limit to which the lowest level can be achieved within specified limits of precision and accuracy. (DOE QSM)

Requirement:

Denotes a mandatory specification; often designated by the term "shall". (NELAC)

Resource

The enabling legislation that gives the EPA the authority to control

Conservation and Recovery Act (RCRA):

hazardous waste from the "cradle-to-grave", including its generation, transportation, treatment, storage, and disposal. (NELAC)

Retention Time:

The time between sample injection and the appearance of a solute peak at the detector. (DoD QSM)

Revocation:

The total or partial withdrawal of a laboratory's accreditation by the accrediting authority. (NELAC)[4.4.3]

Rounding Rules:

If the figure following those to be retained is less than 5, the figure is dropped, and the retained figures are kept unchanged. As an example, 11.443 is rounded to 11.44. If the figure following those to be retained is greater than 5, the figure is dropped, and the last retained figure is raised by 1. As an example, 11.446 is rounded to 11.45. If the figure following those to be retained is 5, and if there are no figures other than zeros beyond the five, the figure 5 is dropped, and the last-place figure retained is increased by one if it is an odd number or it is kept unchanged if an even number. As an example, 11.435 is rounded to 11.44, while 11.425 is rounded to 11.42. If a series of multiple operations is to be performed (add. subtract, divide, multiply), all figures are carried through the calculations. Then the final answer is rounded to the proper number

of significant figures.

Safe Drinking Water Act (SDWA):

The enabling legislation that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations. (NELAC)

Sample:

A single container or series of containers identified by a unique number comprised of material drawn from a single location or a composite of locations during a fixed period representative of that location (s) and time period(s) for the purpose of analytical testing or physical evaluation. (DOE OSM)

Sample Tracking:

Procedures employed to record the possession of samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a Chain of Custody Form that documents the collection, transport, and receipt of samples to the laboratory. (NELAC)

Secondary Accrediting Authority:

The Territorial, State, or Federal agency that grants NELAC accreditation to laboratories, based upon their accreditation by a NELAP-recognized Primary Accrediting Authority.

(NELAC)[1.5.2.3]

Selectivity:

(Analytical chemistry) The capability of a test method or instrument to respond to a target substance in the presence of non-target

substances. (EPA-QAD)

Sensitivity:

Capability of method or instrument to discriminate between measurement responses representing different levels (e.g. concentrations) of a variable of interest. (NELAC)

Shall:

Denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification as long as the

requirement is fulfilled. (ANSI)

Should:

Denotes a guideline or recommendation whenever noncompliance with the specification is permissible. (ANSI)

Signal-to-Noise Ratio:

The signal carries information about the analyte, while noise is made up of extraneous information that is unwanted because it degrades the accuracy and precision of an analysis and also places a lower limit on the amount of analyte that can be detected. In most measurements, the average strength of the noise is constant and independent of the magnitude of the signal. Thus, the effect of noise on the relative error of a measurement becomes greater and greater as the quantity being measured (producing the signal) decreases in amplitude. (DoD OSM)

Spike:

A known mass of target analyte added to a blank sample or a subsample; used to determine recovery efficiency or for other quality control purposes. (NELAC)

Split Sample:

A portion or subsample of a total sample obtained in such a manner that is not believed to differ significantly from other portions of the same sample.

Standard:

A substance or material the properties of which are believed to be known with sufficient accuracy to permit its use to evaluate the same property in a sample.

Standard (2):

The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies. (ASOC)

Standard Blank:

A calibration standard consisting of the same solvent/reagent matrix used to prepare the calibration standards without the analytes. It is used to construct the calibration curve by establishing instrument background.

Standard Operating Procedure (SOP):

A written document which details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing routine and repetitive tasks. (QAMS)

Standard Reference Material (SRM):

A certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method. (EPA-QAD)

Standard (spike) Addition In radiochemistry, the addition of a known quantity of a radiotracer to a sample and to a split or splits of a sample. Both the sample and split(s) are then processed through the method and the difference in response between the samples used to correct for overall bias resulting measurement bias and from losses during preparation. This method of internal calibration is used in radiochemical determinations where isotopic differentiation between target analyte and tracer is not possible.

Statistical Minimum Significant Difference (SMSD): The minimum difference between the control and a test concentration that is statistically significant, a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, and the type of statistical analysis. If the viability remains constant, the sensitivity of the test increases as the number of replicates is increased. (NELAC)

Supervisor (however named):

The individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of equation, training and experience to perform the required analyses. (NELAC)

Surrogates:

A substance with properties that mimic the analyte of interest. It is unlikely to be found in environmental samples and is added to them for quality control purposes. (QAMS)

Suspension: Temporary removal of a laboratory's accreditation for a defined

period of time, which shall not exceed six months, to allow the laboratory time to correct deficiencies or area of non-compliance

with the NELAC standards. (NELAC)[4.4.2]

Systems Audit: A thorough, systematic, qualitative on-site assessment of the

facilities, equipment, personnel, training, procedures, record

keeping, data validation, data management, and reporting aspects of

a total measurement system. (EPA-QAD)

Target analytes: Identified on a list of project-specific analytes for which laboratory

analysis is required.

Technical Director: Individual(s) who has overall responsibility for the technical

operation of the environmental testing laboratory. (NELAC)

Technical Detailed instructions identifying the specific analysis or parameter

Requirements: desired and the requested regulatory method of analysis. Any deviation(s) from the regulatory methods regarding preparation and

analysis protocol(s) and/or reporting will be defined. (DOE QSM)

Technology: A specific arrangement of analytical instruments, detection systems,

and/or preparation techniques. (NELAC)

Test: A technical operation that consists of the determination of one or

more characteristics or performance of a given product, material, equipment, physical phenomenon, process, or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.

(ISO/IEC Guide 2-12.1, amended)

Test Method: An adoption of a scientific technique for a specific measurement

problem, as documented in a laboratory SOP or published by a

recognized authority. (NELAC)

Testing Laboratory: A laboratory that performs tests. (ISO/IEC Guide 2-12.4)

Test The minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent

on the number of replicates per concentration, the selected

significance level, and the type of statistical analysis. (NELAC)

Tolerance Chart: A chart in which the plotted quality control data is assessed via a

tolerance level (e.g. +/-10% of a mean) based on the precision level

judged to be acceptable to meet overall quality/data use

requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma) (applies to radio bioassay laboratories). (ANSI)

Toxic Substances
Control Act (TSCA):

The enabling legislation that provides for testing, regulating, and screening all chemicals produced or imported into the United States for possible toxic effects prior to commercial manufacture. (NELAC)

Total Propagated Uncertainty (TPU)

An estimate of the total error, including counting uncertainty, associated with a single radiochemical measurement for a single sample.

Traceability:

The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons. (VIM-6.12)

Tracer:

A radionuclide that chemically mimics and does not interfere with the target radioanalyte through the chemical preparation and instrument analysis. (DOE QSM)

Tracer Chemical Recovery:

The percent yield of the recovered radioisotope after the sample/tracer aliquot has undergone preparation and instrument analysis. (DOE OSM)

Trip Blank:

This blank is used to detect sample contamination from the container and preservative during transport and storage of the sample. A cleaned sample container is filled with laboratory pure water; any preservative used in the sample is added; and then the blank is stored, shipped, and analyzed with its group of samples. See Blank.

Tune:

An injected standard required by the method as a check on instrument performance for mass spectrometry. (DoD QSM)

United States Environmental Protection Agency (EPA): The federal governmental agency with responsibility for protecting public health and safeguarding and improving the natural environment (i.e. the air, water, and land) upon which human life depends. (US-EPA)

Unsupported Nuclide:

A daughter nuclide, which has been removed from the parent(s) in the decay chain in which it was produced. (DOE QSM)

Validation:

Confirmation by examination and provision of evidence that specified requirements have been met. (EPA-QAD)

Verification:

Confirmation by examination and provision of evidence that specified requirements have been met. (NELAC) NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore in service, to perform adjustment, to repair or downgrade, or declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

Warning Limits

The limits (typically 2 standard deviations either side of the mean) shown on a control chart within which most results are expected to lie (within a 95% probability) while the system remains in a state of statistical control.

14.2 ACRONYMS

AA DEFINITION
AA Atomic absorption

Ac Actinium ACN Acetonitrile

ACS American Chemical Society
ADC Analog to Digital Converter

AFCEE Air Force Center for Environmental Excellence

AFIID Air Force installation identification

Ag Silver

AgNO₃ Silver Nitrate

A2LA American Association for Laboratory Accreditation

Al Aluminum
AL Action Level
Am Americium

ANSI/ASQC American National Standards Institute/American Society for Quality Control

AOAC Association of Analytical Chemistry

APHIS USDA Animal and Plant Health Inspection Service

API American Petroleum Institute

ARAR Applicable or relevant and appropriate requirement

Ar Argon As Arsenic

ASCII American Standard Code Information Interchange

AST Aboveground Storage Tank

ASTM American Society for Testing and Materials

At Astatine Au Gold

B Boron Ba Barium

BC Background Counts

Be Bervllium

BEP Bis(2-ethylhexyl)phthalate
BFB Bromofluorobenzene

BHC Benzene Hexachloride (Lindane)
BHT Butylated Hydroxytoluene

Bi Bismuth

BIPM Bureau International des Poids et Mesures

Bk Berkelium

BLM Bureau of Land Management

BNA Base-Neutral and Acid Extractable Organic Compounds

BOD Biochemical Oxygen Demand

BP Boiling Point

Bq Becquerels
Br- Bromide
BS Blank Spike

BTEX Benzene, toluene, ethylbenzene, xylene

C Carbon

°C Degrees Celsius

Ca Calcium

CA Corrective Action CAA Clean Air Act CaCl₂ Calcium Chloride CAP Corrective Action Plan CAR Corrective Action Report CAS Chemical Abstract Service CCC Calibration check compound CCB Continuing Calibration Blank Continuing calibration verification CCV

Cd Cadmium

CDPHE Colorado State Department of Public Health and the Environment

CDTA Cyclohexylenediamine tetraacetic acid

Ce Cerium

CERCLA Comprehensive Environmental Response, Compensation, and Liability Act

C₆H₁₄ Hexane
CH₃COCH₃ Acetone
Ci Curies
Cf Californium
CF Calibration factor
CFC Chlorofluorocarbons

CFR Code of Federal Regulation

CH₂Cl₂ Methylene Chloride

CH₃OH Methanol
Cl Chlorine
CL Control limit

CLLE, CLE Continuous Liquid-Liquid Extractor

CLP Contract Laboratory Program

Cm Curium Co Cobalt

COC Chain of custody

COD Chemical Oxygen Demand

CPM Counts per Minute

Cr Chromium

CRDL Contract Required Detection Limit

Cs Cesium Cu Copper

CuSO₄ Copper Sulfate

CV Coefficient of variation

CVAA Cold Vapor Atomic Absorption Spectroscopy.

CWA Clean Water Act

D Drift or Difference

2,4-D 2,4 dichlorophenoxy acetic acid 2,4-DB 2,4 dichlorophenoxy butyric acid DBCP 1,2-Dibromo-3-chloropropane

DCA Dichloroethane

DCAA 2,4-Dichlorophenylacetic acid

DCB Dichlorobenzene
DCBP Decachlorobiphenyl
DCE Dichloroethene
DCM Dichloromethane
DCP Dichlorophenol

DDD Dichlorodiphenyldichloroethane
DDE Dichlorodiphenyldichloroethane
DDT Dichlorodiphenyltrichloroethane

DDVP Dichlorvos

DENIX Defense Environmental Management Information Exchange
DEQPPM Defense Environmental Quality Program Policy Memorandum

DER Duplicate Error Ratio

DFTPP Decafluorotriphenylphosphine

DI Deionized
DL Decision Level
DMG Dimethylgloxime
DNB Dinitrobenzene
DNT Dinitrotoluene

DOC Demonstration of capability
DoD Department of Defense
DOE Department of Energy

DOT Department of Transportation

DPC Diphenylcarbazide

DPM Disintegrations per Minute
DQI Data Quality Initiative
DQO Data quality objective
DRO Diesel range organics

Dy Dysprosium

EB Equipment Blank

ECD Electron Capture Detector

EDB Ethylene dibromide

EDD Electronic Data Deliverable

EERF Eastern Environmental Radiation Facility

EICP Extracted ion current profile

EMSL Environmental Monitoring Systems Laboratory

EPA Environmental Protection Agency

Er Erbium
Eu Europium
EV Electron Volts
Es Einsteinium
Et₂O Diethyl ether

F Fahrenheit
F Fluoride
FB Field Blank
FD Field Duplicate

Fe Iron

FID Flame ionization detector

FIFRA Federal Insecticide, Fungicide, and Rodenticide Act

FLAA Flame atomic absorption

Fm Fermium

FPD Flame Photometric Detector

Fr Francium
FR Federal Register
FS Feasibility study
FSP Field sampling plan

Ft Feet or foot

FWHM Full width at half maximum

FWPCA Federal Water Pollution Control Act (CWA)

g/L Grams per liter

G Glass
Ga Gallium

GAC Granulated Activated Carbon
GALP Good Automated Lab Practice

GC Gas chromatography

GC/MS Gas chromatography/mass spectrometry

Ge Germanium Gd Gadolinium

GFAA Graphite furnace atomic absorption
GFPC Gas Flow Proportional Counting
GPC Gel Permeation Chromatography

GRO Gasoline range organics

GW Groundwater

GWM Groundwater Monitoring

GWPS Groundwater Protection Standard
GWTP Groundwater Treatment Plant

H Hydrogen

Handbook Handbook for the Installation Restoration Program (IRP) Remedial

Investigation and Feasibility Studies (RI/FS), September 1993

HASL Health and Safety Laboratory

HC Hydrocarbons HCl Hydrochloric acid

He Helium

HECD (Hall) electrolytic conductivity detector

HEM Hexane Extractable Material
HpCDD Heptachlorodibenzo-p-dioxin
HpCDF Heptaclorordibenzofuran
HxCDD Hexachlorodibenzo-p-dioxin
HxCDF Hexachlorodibenzofuran
HDPE High-Density Polyethylene

Hf Hafnium

HF Hydrofluoric acid

Hg Mercury

Hg(NO₃)₂ Mercuric Nitrate

HLW High Level Radioactive Waste

HMX Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine

HNO₃ Nitric acid Ho Holmium

HOAc Glacial Acetic Acid

HPGe High Purity Germanium Gamma Spectrometer HPLC High-performance liquid chromatography

H₃PO₄ Phosphoric acid

HSL Hazardous Substances List HSO Health and Safety Officer

H₂SO₄ Sulfuric acid

HVAC Heating, Ventilation, Air Conditioning

I Iodine

IAW In accordance with IC Ion Chromatography

ICAP Inductively Coupled Argon Plasma

ICB Initial Calibration Blank
ICOC Internal Chain of Custody
ICP Inductively coupled plasma

ICPES Inductively coupled plasma emission spectroscopy ICP-MS Inductively coupled plasma - mass spectrometry

ICS Interference check standard ICV Initial calibration verification ID Identification, identifier

ID Inner Diameter

IDL Instrument Detection Limit

IEEE Institute of Electrical and Electronic Engineers

In Indium

INEEL Idaho National Engineering and Environmental Laboratory

IPC Instrument Performance Check

IPEP Integrated Performance Evaluation Program

IPN Incoming Project Notice
IPR Initial Precision and Recovery

Ir Iridium IR Infrared

IR Installation Restoration

IRP Installation Restoration Program

IRPIMS Installation Restoration Program Information Management System

IS Internal standard

ISO/IEC International Standards Organization/International Electrotechnical Commission

K Potassium

KCl Potassium Chloride KCN Potassium Cyanide KD Kuderna Danish

KHP Potassium Hydrogen Phthalate

KH₂PO₄ Potassium Phosphate KMnO₄ Potassium Permanganate

KNO₃ Potassium Nitrate
KOH Potassium Hydroxide

KPA Kinetic Phosphorescence Analyzer

Kr Krypton

L Liter
La Lanthanum

LC Liquid Chromatography
LCL Lower control limit

LCS Laboratory control sample
LD Laboratory Duplicate
LFB Laboratory Fortified Blank
LFM Laboratory Fortified Matrix

Li Lithium

LIMS Laboratory Information Management System

LLRW Low Level Radioactive Waste
LQAP Laboratory Quality Assurance Plan

Lr Lawrencium

LRB Laboratory Reagent Blank
LSC Liquid Scintillation Counting

Lu Lutetium

LUFT Leaking Underground Fuel Tank
LUST Leaking Underground Storage Tank

MAPEP Mixed Analyte Performance Evaluation Program

MB Method Blank

MCA Multichannel Analyzer

MCAWW Methods for Chemical Analysis of Waters and Wastes

MCPA (4-chloro-2-methylphenoxy) acetic acid

MCPP 2-(4-chloro-2-methylphenoxy) propionic acid

Md Mendelevium

MDA Minimum Detectable Activity

MDC Minimum Detectable Concentration

MDL Method detection limit

MEK Methyl Ethyl Ketone (2-Butanone)

MeOH Methanol Mg Magnesium

MgCl₂ Magnesium Chloride
mg/kg Milligrams per kilogram
mg/L Milligrams per liter
MIBK Methyl Isobutyl Ketone

mmhos/m millimhos/meter
ML Minimum Level

mL Milliliter
mm Millimeter
Mn Manganese
Mo Molybdenum

MQO Measurement quality objective

MS Mass Spectrometer

MS Matrix spike

MSA Method of Standard Additions
MSA Methods of Soil Analysis
MSD Matrix spike duplicate
MSDS Material Safety Data Sheet

MSL Mean Sea Level
MTBE Methyl tert-butyl ether
MW Molecular Weight

N Nitrogen Na Sodium

N/A Not applicable
NaBr Sodium Bromide
NaCl Sodium Chloride
NaF Sodium Fluoride

NAMP National Analytical Management Program

NaNO₂ Sodium Nitrite
NaNO₃ Sodium Nitrate
NaOCl Sodium Hypochlorite
NaOH Sodium Hydroxide

Na₂SO₄ Sodium Sulfate Na₂S₂O₃ Sodium thiosulfate

Nb Niobium

NBS National Bureau of Standards

NC Nitrocellulose

NCP National Contingency Plan NCR Nonconformance Report

NCSL National Conference of Standards Laboratories

Nd Neodymium ND Non Detect

Ne Neon

NEIC National Enforcement and Investigations Center

NELAC National Environmental Laboratory Accreditation Conference NELAP National Environmental Laboratory Accreditation Program

NEPA National Environmental Policy Act
NERL National Exposure Research Laboratory

NESHAP National Emission Standards for Hazardous Air Pollutants

NFESC Naval Facilities Engineering Service Center

NG Nitroglycerin

ng/L Nanograms per liter
ng/mL Nanograms per milliliter
(NH₄)₂PO₄ Ammonium Phosphate

Ni Nickel

NIL Nuclear Inventory Log

NIOSH National Institute for Occupational Safety and Health

NIRP Navy Installation Restoration Program

NIST National Institute of Standards and Technology

NJDEPE New Jersey Department of Environmental Protection and Energy

nmNanometerNoNobeliumNO2NitriteNO3NitrateNpNeptunium

NPDES National Pollutant Discharge Elimination System

NTU Nephelometric turbidity unit

NVLAP National Voluntary Laboratory Accreditation Program

O Oxygen

OCDD Octachlorodibenzo-p-dioxin

OEM Office of Environmental Management

OD Outer Diameter

OPR Ongoing Precision and Recovery
ORD Office of Research and Development

ORP Oxidation-reduction potential

Os Osmium

OSHA Occupational Safety and Health Administration

OVA Organic vapor analyzer

P Phosphorus
P Polyethylene
Pa Protactinium

PAH Polynuclear aromatic hydrocarbon

PARCC Precision, Accuracy, Representativeness, Completeness, Comparability

Pb Lead

PbCrO₄ Lead Chromate

PBMS Performance based measurement system

PCB Polychlorinated biphenyl

PCDD Polychlorinated dibenzo-p-dioxin
PCDF Polychlorinated dibenzofuran
PeCDD Pentachlorodibenzo-p-dioxin
PeCDF Pentachlorodibenzofuran

PCE Perchloroethylene, also Tetrachloroethene

PCP Pentachlorophenol

Pd Palladium

PE Performance Evaluation Sample

PEG Polyethylene Glycol

PEL Permissible Exposure Limit

PEP Performance Evaluation Program

PETN Pentaerthrite tetranitrate
PID Photoionization detector

Pm Promethium
PM Project Manager
PMT Photomultiplier Tube

PNA Polynuclear aromatic hydrocarbon

PO₄ Phosphate
PP Polypropylene
ppb Parts per billion
ppm Parts per million

ppmv Parts per million volume

Po Polonium

PQL Practical quantitation limit psi Pounds per square inch

Pt Platinum

PT Proficiency testing
PTFE Polytetrafluoroethylene

PTOB/PTBA Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor

POTW Publicly Owned Treatment Works

Pr Praseodymium
Pu Plutonium

PVC Polyvinyl Chloride

QA Quality assurance

QAC Quality Assurance Coordinator
QAD Quality Assurance Division (EPA)
QAMS Quality Assurance Management Section

QAP Quality Assurance Plan

QAPjP Quality assurance project plan QASS Quality Assurance Summary Sheet

QC Quality control

QIP Quench Indicating Parameter

QL Quantitation Limit
QSM Quality Systems Manual

r Correlation Coefficient

R Recovery Ra Radium

RASL Radiological and Environmental Sciences Laboratory

Rb Rubidium

RB Rinse Blank, Reagent Blank

RCA Recommendations for corrective action
RCRA Resource Conservation and Recovery Act
RDX Hexahydro-1,3,5-triazine

Re Rhenium

RF Response factor
RFP Request for Proposal

Rh Rhodium

RI Remedial investigation

RI/FS Remedial investigation/feasibility study

RL Reporting Limit

RMDC Requested Minimum Detectable Concentration

Rn Radon

ROI Region of Interest

RRF Relative Response Factor
RRL Requested reporting limit
RPD Relative percent difference
RPM Revolutions per minute
RRT Relative Retention Time
RSD Relative standard deviation
RSO Radiation Safety Officer

RT Retention Time

RTW Retention Time Window

Ru Ruthenium

s Standard Deviation

S second

S Sulfur S Soil

SAP Sampling and analysis plan

SARA Superfund Amendments and Reauthorization Act

Sb **Antimony** Sc Scandium

SD Standard Deviation **SDWA** Safe Drinking Water Act

Se Selenium Si Silicon Sm Samarium

SM Standard Method

SMSD Statistical Minimum Significant Difference

Sn Tin SO₄ Sulfate

SOP Standard operating procedure

SOW Statement of work

SPCC System performance check compound SPLP, SLP Synthetic Precipitation Leaching Procedure

SPV Software Process Validation

Sr Strontium

SRM Standard Reference Material

SS Stainless Steel SS Surrogate Standard

SSSA Soil Science Society of America STEL Short Term Exposure Limit **SVOC** Semivolatile organic compound

SW Surface Water SW Solid Waste

2,4,5-T 2,4,5-trichlorophenoxy acetic acid

California brass Ta

Tantalum

TAL Target Analyte List

Th **Terbium** TB Trip Blank Tc Technetium

TC **Toxicity Characteristic**

TCA Trichloroethane

TCDD Tetrachlorodibenzo-p-dioxin **TCDF** Tetrachlorodibenzofuran

TCE Trichloroethene

TCLP Toxicity characteristic leaching procedure

TCMX Tetrachlorometaxylene TCL Target Compound List TCP Trichlorophenol

TDS Total Dissolved Solids

Te Tellurium

TEPP Tetraethyl pyrophosphate

TFS Total Fixed Solids
TFT Trifluorotoluene

Th Thorium

THAM Tris(hydroxymethyl)aminomethane
THE Total Extractable Hydrocarbons

THF Tetrahydrofuran THM Trihalomethane

Ti Titanium

TIC Tentatively identified compound

Tl Thallium

TLV Threshold Limit Value

Tm Thulium

TNB Trinitrobenzene
TNT Trinitrotoluene
TOC Total Organic Carbon

TOX Total Organic Halogens

2,4,5-TP 2,4,5-trichlorophenoxy acetic acid (silvex)

TPH Total petroleum hydrocarbon
TPU Total Propagated Uncertainty
TQM Total Quality Management

TRPH Total Recoverable Petroleum Hydrocarbons

TSCA Toxic Substances Control Act

TSDF Treatment, Storage, and Disposal Facility

TS Total Solids

TSS Total suspended solids

TVPH Total Volatile Petroleum Hydrocarbons

TVS Total Volatile Solids

U Uranium

UCL Upper control limit
UF Uncertainty Factor

UPS Uninterruptible Power Supply

USACE United Stated Army Corp of Engineers
USDA United States Department of Agriculture

USEPA United States Environmental Protection Agency

USGS United States Geological Survey UST Underground Storage Tank

UV Ultraviolet

UXO Unexploded Ordnance

V	Volume
V	Volts
V	Vanadium
VC	Vinyl Chloride
VOA	Volatila Orona

VOA Volatile Organic Analysis VOC Volatile organic compound

v/v Volume to volume

W Tungsten Water

WDC Waste Disposal Coordinator

WET Waste Extraction Test

WO Work Order WP Water Pollution

WQS Water Quality Standard

WS Water Study w/v Weight to volume

Xe Xenon

Yb Ytterbium Y Yttrium

ZHE Zero Headspace Extraction

Zn Zinc Zirconium

14.3 SYMBOLS

Symbol	<u>Definition</u>	
Length		
um	micrometer	10 ⁻⁶ meter
mm	millimeter	10 ⁻³ meter
cm	centimeter	0.01 meter
dm	decimeter	0.1 meter
m	meter	0.1
Weight		
pg	picogram	10 ⁻¹² gram
ng	nanogram	10 ⁻⁹ gram
ug	microgram	10 ⁻⁶ gram
mg	milligram	10 ⁻⁹ gram 10 ⁻⁶ gram 10 ⁻³ gram
g	gram	•
Kg	kilogram	10 ³ gram
Volume		
uL	microliter	10 ⁻⁶ Liter
mL	milliliter	10 ⁻³ Liter
dL	deciliter	0.1 Liter
L	liter	
Concentration		
ng/ul	nanogram per microliter	
ug/L	microgram per liter	
ug/kg	microgram per kilogram	
ug/g	microgram per gram	
ug/mL	microgram per milliliter	
mg/kg	milligram per kilogram	
mg/L	milligram per liter	
ug/m ³	microgram per cubic	
nnh	meter	
ppb	part per billion	
ppm	part per million	
Time		
s or sec	second	1/60 minute
m or min	minute	60 seconds, 1/60 hour
h	hour	60 minutes
		·

Temp	eratui	re
------	--------	----

°C		degree Celsius
°F		degree Fahrenheit
K	-	degree Kelvin

Activity

Bq	bequerel	Disintegration/s
Ci	Curie	$3.7 \times 10^{10} \text{Bq}$
dom	disintegration per minute	

Electrical

V	Volt
A	Ampere
EV	Electron volt
F	Farad
Ω	ohm
S or mho	Siemens
W	Watt

Prefixes

tera	1012
giga	10 ⁹
mega	10^{6}
kilo	10 ³
hecto	10^2
deca	10
deci	0.1
centi	10 ⁻²
milli	10 ⁻³
micro	10 ⁻⁶
nano	10-9
pico	10 ⁻¹²
femto	10 ⁻¹⁵